

Exhibit

“2”

Alan Garely, M.D., FACOG, FACS

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC Master File No.
REPAIR SYSTEM PRODUCTS 2:12-MD-02327
LIABILITY LITIGATION MDL 2327
U.S. DISTRICT JUDGE
JOSEPH R.
GOODWIN

Deposition of ALAN GARELY, M.D., relating to the
following cases in Wave 1 of MDL 200:

Carey Beth Cole, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00483

Amanda Deleon, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00358

Rose Gomez, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00344

Donna Zoltowski, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00811

DEPOSITION OF ALAN GARELY, M.D., FACOG, FACS

Friday, April 15, 2016

New York, New York

GOLKOW TECHNOLOGIES, INC.

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Alan Garely, M.D., FACOG, FACS

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<p>1 Deposition of ALAN GARELY, M.D., FACOG, FACS</p> <p>2 pursuant to Notice, on the the 15th day of April 2016,</p> <p>3 at Loews Regency Hotel, 540 Park Avenue & 61st Street</p> <p>4 New York, New York, commencing at 9:00 a.m.;</p> <p>5 before DANA N. SREBRENICK, a Certified Court</p> <p>6 Reporter, a Registered Realtime Reporter and</p> <p>7 Notary Public within and for the State of New</p> <p>8 York.</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1</p> <p>2 APPEARANCES: (Continued.)</p> <p>3</p> <p>4 On behalf of Defendant:</p> <p>5 BUTLER SNOW, LLP</p> <p>6 1020 Highland Colony Parkway</p> <p>7 Suite 1400</p> <p>8 Ridgeland, Mississippi 39157</p> <p>9 601.948.5711</p> <p>10 BY: PAUL S. ROSENBLATT, ESQ.</p> <p>11 paul.rosenblatt@butlersnow.com</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
Page 3	Page 5
<p>1</p> <p>2 APPEARANCES:</p> <p>3</p> <p>4 On behalf of Plaintiff:</p> <p>5 BLASINGAME, BURCH, GARRARD, ASHLEY, P.C.</p> <p>6 440 College Avenue</p> <p>7 Suite 320</p> <p>8 Athens, Georgia 30601</p> <p>9 706.354.4000</p> <p>10 BY: JAMES B. MATTHEW, ESQ.</p> <p>11 Jbm@bbgbalaw.com</p> <p>12</p> <p>13 On behalf of Defendant:</p> <p>14 RIKER DANZIG SCHERER HYLAND &</p> <p>15 PERRETTI, LLP</p> <p>16 Headquarters Plaza</p> <p>17 One Speedwell Avenue</p> <p>18 Morristown, New Jersey 07962</p> <p>19 973.538.0800</p> <p>20 BY: MAHA M. KABBASH, ESQ.</p> <p>21 Mkabbash@riker.com</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 - - -</p> <p>2 I N D E X</p> <p>3 - - -</p> <p>4</p> <p>5 Testimony of:</p> <p>6 ALAN GARELY, M.D., FACOG, FACS</p> <p>7 BY MS. KABBASH..... 9</p> <p>8</p> <p>9 - - -</p> <p>10 E X H I B I T S</p> <p>11 - - -</p> <p>12 GARELY</p> <p>13 NO. DESCRIPTION PAGE</p> <p>14 Exhibit 1 Notice to take Deposition</p> <p>15 of Alan Garely, M.D..... 11</p> <p>16 Exhibit 4 Disk with reference</p> <p>17 documents..... 13</p> <p>18 Exhibit 5 Flask drive with reliance</p> <p>19 list documents..... 13</p> <p>20 Exhibit 2 Dr. Garely's Prolift</p> <p>21 Expert Report..... 14</p> <p>22 Exhibit 3 Dr. Garely's Prolift+M</p> <p>23 Expert Report..... 14</p> <p>24</p> <p>25</p>

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1	- - -				1	- - -			
2	E X H I B I T S (Continued.)				2	E X H I B I T S (Continued.)			
3	- - -				3	- - -			
4	GARELY				4	GARELY			
5	NO. DESCRIPTION PAGE				5	NO. DESCRIPTION PAGE			
6	Exhibit 6 Dr. Garely's Curriculum				6	Exhibit 17 Document entitled Pelvic			
7	Vitae.....22				7	Organ Prolapse and Sexual			
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10	ETH.MESH.08622118.....63				10	B, Dr. Garely's review			
11	Exhibit 8 Printout from Alan				11	materials.....249			
12	Garely, M.D.'s website89				12				
13	Exhibit 9 Handwritten estimation of				13				
14	prior TVT retropubics				14				
15	performed by Dr. Garely....108				15				
16	Exhibit 10 Handwritten notes by Dr.				16				
17	Garely estimating number				17				
18	of TVT-O brand slings and				18				
19	obturator slings that				19				
20	he's performed119				20				
21	Exhibit 11 Document entitled				21				
22	Position Statement on				22				
23	Mesh Midurethral Slings				23				
24	for Stress Urinary				24				
25	Incontinence.....120				25				

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1	- - -				1	ALAN GARELY, MD, FACOG, FACS, having			
2	E X H I B I T S (Continued.)				2	first been duly sworn by the Notary Public of			
3	- - -				3	the State of New York, was examined and			
4	GARELY				4	testified as follows:			
5	NO. DESCRIPTION PAGE				5	- - -			
6	Exhibit 12 Document entitled				6	EXAMINATION BY MS. KABBASH:			
7	Surgeon's Resource				7	- - -			
8	Monograph on Gynecare TVT..123				8	Q Good morning, Dr. Garely. I'll			
9	Exhibit 13 Document entitled				9	introduce myself again. My name is Maha Kabbash			
10	Gynecare TVT with				10	and I work for the Riker Danzig firm in			
11	abdominal guides, Early				11	Morristown, New Jersey, and I represent the			
12	Clinical Experience.....129				12	defendants in the litigation, Johnson & Johnson			
13	Exhibit 14 Document entitled Oxford				13	and Ethicon. And I'm here with my colleague,			
14	Levels of Evidence				14	Paul Rosenblatt, from the Butler Snow firm.			
15	Pyramid for Practitioners..147				15	And we are here to take your deposition			
16	Exhibit 15 Document entitled				16	on your general opinions on Prolift and			
17	Magnetic Resonance				17	Prolift+M in the Ethicon litigation.			
18	Imaging of Abdominal				18	And I understand that your opinions			
19	versus Vaginal Prolapse				19	have been served in four cases that I'll just			
20	Surgery with Mesh.....151				20	put on the record, Carey Beth Cole, Amanda			
21	Exhibit 16 Document entitled				21	Deleon, Rose Gomez and Donna Zoltowski.			
22	Gynecare Prolift				22	So thank you for your time in being			
23	Surgeon's Resource				23	here today.			
24	Monograph.....219				24	A Thank you.			
25									

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<p style="text-align: right;">Page 10</p> <p>1 Q I have in front of you -- I should</p> <p>2 start out -- and, sir, I understand that you've</p> <p>3 been deposed -- how many times have you been</p> <p>4 deposed in the past in this litigation or in any</p> <p>5 litigation?</p> <p>6 A In against product liability or in</p> <p>7 general?</p> <p>8 Q Anything. How many depositions have</p> <p>9 you ever given?</p> <p>10 A Probably somewhere between eight and</p> <p>11 12.</p> <p>12 Q So you're very familiar then with the</p> <p>13 process of a deposition. I'll just tell you two</p> <p>14 things; first, it's important that we try as</p> <p>15 much as we can not to talk over each other so</p> <p>16 that the court reporter doesn't have to try to</p> <p>17 take down what we're both saying at the same</p> <p>18 time.</p> <p>19 And also, if I ask a question that you</p> <p>20 don't understand or that just doesn't make sense</p> <p>21 medically or otherwise, please let me know and</p> <p>22 I'll do my best to clarify it. And if you</p> <p>23 answer a question that I asked, I will assume</p> <p>24 that you understood it, okay?</p>	<p style="text-align: right;">Page 12</p> <p>1 footnotes, a CD which consists of the same</p> <p>2 things, and a thumb drive which contains all of</p> <p>3 the materials that he considered in forming his</p> <p>4 opinions in this case. Everything that he was</p> <p>5 sent is on the thumb drive.</p> <p>6 MS. KABBASH: Okay. What's the</p> <p>7 difference between what's on the disk and what's</p> <p>8 on the thumb drive?</p> <p>9 MR. MATTHEWS: The thumb drive is</p> <p>10 Exhibit B to his report, which is the whole</p> <p>11 reliance list. What's on the disk is simply</p> <p>12 those documents that are referenced in</p> <p>13 footnotes.</p> <p>14 MS. KABBASH: I see.</p> <p>15 MR. MATTHEWS: So the disk is much</p> <p>16 shorter than the thumb drive. This has got</p> <p>17 hundreds or thousands of documents on it.</p> <p>18 MS. KABBASH: Okay.</p> <p>19 MR. MATTHEWS: This has 100, maybe.</p> <p>20 BY MS. KABBASH:</p> <p>21 Q So the disk contains the documents that</p> <p>22 are referenced in the footnotes of your report,</p> <p>23 Dr. Garely, correct?</p> <p>24 A Yes, ma'am.</p>
<p style="text-align: right;">Page 11</p> <p>1 A Yes, ma'am.</p> <p>2 Q I've put in front of you a dep notice,</p> <p>3 which is marked as Exhibit Garely 1.</p> <p>4 (Exhibit Garely 1, Notice to take</p> <p>5 Deposition of Alan Garely, M.D., marked for</p> <p>6 identification.)</p> <p>7 BY MS. KABBASH:</p> <p>8 Q And if you look to the fifth page of</p> <p>9 it, there's a series of document requests there</p> <p>10 that requests -- that request various documents</p> <p>11 related to your opinions in this litigation.</p> <p>12 Have you brought documents with you today?</p> <p>13 A Just what Mr. Matthews brought.</p> <p>14 Q Okay. And I know we discussed that a</p> <p>15 little bit off the record, but can you describe</p> <p>16 what you brought with you today, and I'm happy</p> <p>17 to either have you testify about it or to take</p> <p>18 your counsel's representation, either way.</p> <p>19 MR. MATTHEWS: It might be quicker if</p> <p>20 counsel talks.</p> <p>21 MS. KABBASH: I was hoping.</p> <p>22 MR. MATTHEWS: We have copies of his</p> <p>23 expert reports, copies of the documents that are</p> <p>24 referenced in his expert reports via the</p>	<p style="text-align: right;">Page 13</p> <p>1 Q Okay.</p> <p>2 MS. KABBASH: Can I mark both of those?</p> <p>3 MR. MATTHEWS: The notebook too?</p> <p>4 MS. KABBASH: No, the flash drive.</p> <p>5 MR. MATTHEWS: You can mark them and</p> <p>6 you can have them.</p> <p>7 MS. KABBASH: Thank you. I'm going to</p> <p>8 mark the disk that's been produced as Exhibit 4.</p> <p>9 (Exhibit Garely 4, Disk with reference</p> <p>10 documents, marked for identification.)</p> <p>11 MS. KABBASH: And I'll mark -- I'm not</p> <p>12 sure how to mark the flash drive. We'll mark</p> <p>13 the flash drive as Exhibit 5.</p> <p>14 (Exhibit Garely 5, Flash drive with</p> <p>15 reliance list documents, marked for</p> <p>16 identification.)</p> <p>17 BY MS. KABBASH:</p> <p>18 Q Doctor, have you brought with you today</p> <p>19 any invoices regarding your work in the Ethicon</p> <p>20 pelvic mesh litigation?</p> <p>21 A I did not.</p> <p>22 Q Are you prepared to testify about how</p> <p>23 much time you've spent on the litigation in</p> <p>24 Ethicon and how much money you have billed or</p>

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<p>1 are entitled to bill?</p> <p>2 A Roughly, yes.</p> <p>3 Q Why don't we do this, I think we marked</p> <p>4 your report -- I've marked your report as</p> <p>5 Exhibit 2. And I've also marked your -- I</p> <p>6 should say I've marked your Prolift report as</p> <p>7 Exhibit 2 and I've market your Prolift+M report</p> <p>8 as Exhibit 3.</p> <p>9 (Exhibit Garely 2, Dr. Garely's Prolift</p> <p>10 Expert Report, marked for identification.)</p> <p>11 (Exhibit Garely 3, Dr. Garely's</p> <p>12 Prolift+M Expert Report, marked for</p> <p>13 identification.)</p> <p>14 BY MS. KABBASH:</p> <p>15 Q If you could turn to, in your regular</p> <p>16 Prolift report, the last page before the</p> <p>17 footnotes.</p> <p>18 A Would that be page 32?</p> <p>19 Q Page 32, correct.</p> <p>20 A Yes, ma'am.</p> <p>21 Q And you have a section there, section</p> <p>22 5, Compensation for My Review, Study and</p> <p>23 Testimony, correct?</p> <p>24 A Correct.</p>	<p>1 Q When were you first retained to work on</p> <p>2 the -- to work as a plaintiff's expert in the</p> <p>3 Ethicon litigation?</p> <p>4 A I think I was asked if I would</p> <p>5 participate in this review somewhere in the</p> <p>6 summer or fall of 2015, but it could have been</p> <p>7 earlier. I just don't recall.</p> <p>8 Q And at the time that you were retained,</p> <p>9 what were you asked to do?</p> <p>10 A I was asked if I would be willing to</p> <p>11 review the -- the documents and the literature</p> <p>12 regarding the product and see if I felt that</p> <p>13 there were problems with the product, that I</p> <p>14 would be willing to be an expert.</p> <p>15 Q And am I correct that in -- you have</p> <p>16 not issued any case-specific opinions thus far</p> <p>17 in the Ethicon litigation? Do you know what I</p> <p>18 mean by "case-specific opinions"?</p> <p>19 A I do not.</p> <p>20 Q You haven't issued any opinions</p> <p>21 regarding a specific plaintiff and what may have</p> <p>22 caused her alleged injuries?</p> <p>23 A I have reviewed charts on a few</p> <p>24 patients, yes.</p>
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<p>1 Q And does this set forth what your</p> <p>2 hourly rates are and what your half day and full</p> <p>3 rates are for testimony?</p> <p>4 A It does.</p> <p>5 Q So you're charging \$1,000 per hour for</p> <p>6 review and study of records, correct?</p> <p>7 A Correct.</p> <p>8 Q And when you were provided records</p> <p>9 within 30 days of some deadline, you charge an</p> <p>10 additional 50 percent per hour?</p> <p>11 A Correct.</p> <p>12 Q If you provide deposition or trial</p> <p>13 testimony in the litigation, you're charging</p> <p>14 \$6,000 for a half day and \$10,000 for a full</p> <p>15 day?</p> <p>16 A Correct.</p> <p>17 MR. MATTHEWS: Take that into</p> <p>18 consideration.</p> <p>19 MS. KABBASH: I'm assuming you are as</p> <p>20 well.</p> <p>21 BY MS. KABBASH:</p> <p>22 Q And outside of an eight-hour workday if</p> <p>23 you travel, you bill \$250 an hour for that?</p> <p>24 A I do.</p>	<p>1 Q But you haven't issued any opinions yet</p> <p>2 regarding those patients, correct? Strike that.</p> <p>3 You haven't prepared a report that has</p> <p>4 been served in the litigation yet to your</p> <p>5 knowledge?</p> <p>6 A I don't know if it's been served, no.</p> <p>7 Q Okay.</p> <p>8 MR. MATTHEWS: I think there was one.</p> <p>9 MS. KABBASH: Oh.</p> <p>10 BY MS. KABBASH:</p> <p>11 Q You prepared a report in the Katherine</p> <p>12 Grace Erwin case?</p> <p>13 A Correct.</p> <p>14 Q Okay, that's right. I forgot about</p> <p>15 that.</p> <p>16 Is that the only one that you have</p> <p>17 prepared so far?</p> <p>18 A I think there was another one. I</p> <p>19 just -- because I've been focusing on this, I</p> <p>20 haven't looked at those cases and I think there</p> <p>21 was a second one. I just don't remember. If</p> <p>22 you said the name, I might remember.</p> <p>23 Q Am I correct that you have not issued</p> <p>24 opinions regarding Carey Beth Cole?</p>

5 (Pages 14 to 17)

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<p>1 A I don't believe so.</p> <p>2 Q Amanda Deleon?</p> <p>3 A Doesn't sound familiar.</p> <p>4 Q Rose Gomez? As you sit here right now,</p> <p>5 that's not ringing a bell?</p> <p>6 A No.</p> <p>7 Q And Donna Zoltowski?</p> <p>8 A Zoltowski sounds familiar only because</p> <p>9 I may -- I've reviewed so many, that was one</p> <p>10 sounds sort of familiar. I just don't recall if</p> <p>11 I reviewed that one.</p> <p>12 Q Okay. So can you tell me -- have you</p> <p>13 already billed plaintiff's counsel for the work</p> <p>14 that you've done in the Ethicon litigation?</p> <p>15 A I have not.</p> <p>16 Q Can you tell me how many hours you have</p> <p>17 spent so far on the Ethicon litigation to</p> <p>18 include, and you're welcome to break it down if</p> <p>19 you want to, but everything from meeting with</p> <p>20 counsel, from document review, preparing your</p> <p>21 reports, preparing for your deposition today?</p> <p>22 A I think that between the review of</p> <p>23 records and preparation, the total hours from</p> <p>24 the beginning of review to now are going to come</p>	<p>1 Q And you've also been deposed as a</p> <p>2 treating physician, correct?</p> <p>3 A Correct.</p> <p>4 Q What products were involved in the case</p> <p>5 in which you were deposed as a treating</p> <p>6 physician? Was that a Bard product?</p> <p>7 A It was a Bard product.</p> <p>8 Q A Bard sling?</p> <p>9 A I think it was an Avaulta or maybe -- I</p> <p>10 don't -- I think it was an Avaulta, I just don't</p> <p>11 recall.</p> <p>12 Q Are the opinions that you've issued in</p> <p>13 the two reports that we have marked as Exhibit 2</p> <p>14 and 3, are these the first opinions, expert</p> <p>15 opinions that you have issued in litigation</p> <p>16 against Ethicon?</p> <p>17 A Yes, ma'am.</p> <p>18 Q How did you prepare for the deposition</p> <p>19 today?</p> <p>20 A I reviewed literature. I reviewed</p> <p>21 notes that I received from medical conferences</p> <p>22 that I've attended. I have reviewed videos. I</p> <p>23 have -- depended on my knowledge of the product</p> <p>24 in speaking with people from the company and</p>
Page 19	Page 21
<p>1 in somewhere between 250 and 350 hours.</p> <p>2 Q And by and large, those 250 to 350</p> <p>3 hours would be at the hourly rate of \$1,000,</p> <p>4 other than the time that you're in the</p> <p>5 deposition today?</p> <p>6 A Yes, ma'am.</p> <p>7 Q And for the time that you're in the</p> <p>8 deposition today, will you be charging your</p> <p>9 \$10,000 full day rate?</p> <p>10 A I believe so, yes.</p> <p>11 Q Who retained you in this mesh</p> <p>12 litigation, which firm?</p> <p>13 A Blasingame.</p> <p>14 Q And you have been previously retained</p> <p>15 as a plaintiff's expert in other mesh</p> <p>16 litigations as well, correct?</p> <p>17 A Correct.</p> <p>18 Q Is that the Bard litigation also or</p> <p>19 have you been retained in other -- in cases</p> <p>20 against other manufacturers?</p> <p>21 A Just in Bard.</p> <p>22 Q And you were deposed twice in the Bard</p> <p>23 litigation as an expert?</p> <p>24 A Yes, ma'am.</p>	<p>1 other users of the products.</p> <p>2 Q Which videos did you review?</p> <p>3 A There were procedural videos on</p> <p>4 Prolift.</p> <p>5 Q Did you meet with counsel to prepare</p> <p>6 for your deposition?</p> <p>7 A Yes, ma'am.</p> <p>8 Q How many times did you meet?</p> <p>9 A Once.</p> <p>10 Q Did you meet with Mr. Matthews?</p> <p>11 A I did.</p> <p>12 Q And how long was your meeting for?</p> <p>13 A It was for an hour and 40 minutes.</p> <p>14 Q And how long ago was that?</p> <p>15 A It was yesterday.</p> <p>16 Q Did you review any particular documents</p> <p>17 while you were meeting with Mr. Matthews</p> <p>18 yesterday?</p> <p>19 A I did.</p> <p>20 Q Which documents did you review?</p> <p>21 A The documents that are in front of me</p> <p>22 right now.</p> <p>23 Q Your reports?</p> <p>24 A Yes, ma'am.</p>

6 (Pages 18 to 21)

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<p>1 Q Anything other than your reports?</p> <p>2 A No.</p> <p>3 Q How many hours would you say you've</p> <p>4 spent preparing for the deposition?</p> <p>5 A Close to 60.</p> <p>6 Q Let's mark your CV.</p> <p>7 (Exhibit Garely 6, Dr. Garely's</p> <p>8 Curriculum Vitae, marked for identification.)</p> <p>9 BY MS. KABBASH:</p> <p>10 Q Dr. Garely, I've just handed you what's</p> <p>11 been marked as Exhibit 6. Is that your updated</p> <p>12 curriculum vitae?</p> <p>13 A I think I just updated another like</p> <p>14 about two weeks ago. I think I may have added</p> <p>15 something minor to it. I just don't remember</p> <p>16 what.</p> <p>17 Q Do you remember what it was in relation</p> <p>18 to, a published article or a speaking event or</p> <p>19 something along those lines?</p> <p>20 A It was either a publication and I think</p> <p>21 something -- one of my -- I think one of my</p> <p>22 fellows wrote a paper that was either accepted</p> <p>23 for publication or it was presented somewhere so</p> <p>24 I added it.</p>	<p>1 program committee.</p> <p>2 Q I see, thank you.</p> <p>3 A You're welcome.</p> <p>4 Q So you went to medical school at St.</p> <p>5 George's University School of Medicine?</p> <p>6 A I did.</p> <p>7 Q And that was in Grenada in the West</p> <p>8 Indies, correct?</p> <p>9 A That's correct.</p> <p>10 Q After that, you did an internship at</p> <p>11 St. Vincent's OB/GYN department here in New</p> <p>12 York?</p> <p>13 A I did.</p> <p>14 Q And then you did a residency also at</p> <p>15 St. Vincent's in OB/GYN?</p> <p>16 A I did.</p> <p>17 Q And was that -- was your internship and</p> <p>18 residency sort of the same program or were they</p> <p>19 two different programs?</p> <p>20 A One program.</p> <p>21 Q So that was from the time frame from</p> <p>22 1989 to 1993?</p> <p>23 A Yes, I never understood why everybody</p> <p>24 breaks down their internship and residency, but</p>
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<p>1 Q Was that paper that was added, did it</p> <p>2 relate to the use of mesh to treat either stress</p> <p>3 urinary incontinence or prolapse?</p> <p>4 A No.</p> <p>5 Q What was the subject matter of that</p> <p>6 paper?</p> <p>7 A I think it was on -- I think she was</p> <p>8 looking at incisions and patient perceptions.</p> <p>9 Q Uh-huh.</p> <p>10 A Abdominal versus laparoscopic. It had</p> <p>11 nothing to do with vaginal approaches.</p> <p>12 Q Other than that one addition, Doctor,</p> <p>13 does this version of your CV at Exhibit 6 appear</p> <p>14 to be an updated version of your CV and your</p> <p>15 credentials?</p> <p>16 A I think -- actually, I think I remember</p> <p>17 now what I added. I think for the American</p> <p>18 College of Surgeons, I was -- I'm now part of</p> <p>19 the program committee, so I think I updated</p> <p>20 that. My representation to the American College</p> <p>21 of Surgeons from the American Urogynecologic</p> <p>22 Society was also my board representation to the</p> <p>23 Gynecologic Advisory Board was updated. So from</p> <p>24 2015 to present, I'm also the program -- on the</p>	<p>1 everybody does it, so I just did it when I made</p> <p>2 my CV, but it makes no sense.</p> <p>3 Q Did you perform surgeries during that</p> <p>4 time frame, gynecological surgery?</p> <p>5 A As a resident, yes.</p> <p>6 Q What type of surgeries did you perform</p> <p>7 as a resident?</p> <p>8 A Everything that encompasses general</p> <p>9 obstetrics and gynecology, and assisted on</p> <p>10 subspecialty types of surgery with</p> <p>11 fellowship-trained subspecialists.</p> <p>12 Q At that point in time, were you trained</p> <p>13 in doing surgeries to treat prolapse or stress</p> <p>14 urinary incontinence?</p> <p>15 A To the best of everybody's ability at</p> <p>16 that time, I was. They weren't very effective,</p> <p>17 but that's what we learned.</p> <p>18 Q When you say "they weren't very</p> <p>19 effective," what are you referring to?</p> <p>20 A I'm referring to approaches that if</p> <p>21 people did them today, they would be considered</p> <p>22 not the standard of care.</p> <p>23 Q And what were those approaches?</p> <p>24 A To treat stress incontinence, we were</p>

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<p style="text-align: right;">Page 26</p> <p>1 doing things like anterior repairs or needle 2 procedures. To fix prolapse, we were relying on 3 sacrospinous ligament fixations and anterior and 4 posterior repairs for everybody. 5 Q And so what you're saying is it would 6 no longer be the standard of care today to do a 7 sacrospinous ligament fixation or an anterior 8 colpopexy or posterior colpopexy on everybody? 9 A On everybody. I think these operations 10 for sure still have a place. I was more 11 referring to the incontinence procedures as 12 being outdated. 13 Q I see. So you're saying the -- was 14 it -- which operations did you say again? I 15 apologize. 16 A The needle procedures, like staining 17 procedures. 18 Q So the staining procedures and the Ross 19 needle procedures would be considered out of 20 date today, correct? 21 A Correct. 22 Q After your residency at St. Vincent's, 23 you did a fellowship in urogynecology at Mount 24 Sinai at the University of Connecticut, correct?</p>	<p style="text-align: right;">Page 28</p> <p>1 native tissue slings. 2 Q The native tissue slings, is that also 3 referred to as fascial slings? 4 A It can. When I say "native tissue," it 5 implies fascial and also muscle slings. 6 Q What are muscle slings? 7 A So it's where you take the fascia, but 8 you don't just strip it off the muscle, you take 9 the underlying muscle with it, and so it adds a 10 big bulky repair. It's for people who have 11 really severe incontinence or people who have 12 had radiation or a fascial sling won't do the 13 trick. 14 Q Are those types of slings that you're 15 describing to me that involve taking part of the 16 muscle, are those considered out of date today? 17 A I would say that knowing how to do them 18 is beneficial in the rare cases that come up 19 that may need them. I would say the majority of 20 pelvic surgeons that are trained today probably 21 don't know how to do them, which is why when 22 people need those type of surgeries in New York, 23 they'll often refer them to me because they know 24 I have a lot of experience with those.</p>
<p style="text-align: right;">Page 27</p> <p>1 A Correct. 2 Q And that was from 1993 to 1994? 3 A Correct. 4 Q What -- I assume that you were trained 5 in doing urogynecological surgeries during your 6 fellowship, correct? 7 A I was. 8 Q And what types of surgeries did you 9 train in at that time? 10 A The procedures ran the gamut from 11 vaginal approach operations to abdominal 12 approach operations. 13 Q And which ones were they? 14 A For vaginal approach operations, we did 15 anterior/posterior repairs, sacrospinous 16 ligament fixations, uterosacral ligament 17 fixations. We had developed a procedure where 18 we were affixing the vaginal apex to the arcus 19 tendineus. That was sort of a modified 20 paravaginal repair done vaginally. 21 Abdominal approach procedures included 22 sacrocolpopexies, uterosacral ligament 23 suspensions. And then incontinence procedures, 24 such as Burch procedures, MMK procedures, and</p>	<p style="text-align: right;">Page 29</p> <p>1 Q After your fellowship at Mt. Sinai, you 2 did another fellowship in urogynecology at 3 Louisiana State? 4 A LSU, correct. 5 Q Okay. And that was from 1994 to 1995? 6 A Correct. 7 Q And in your second fellowship, did you 8 do the same surgeries as in the first fellowship 9 or were there additional surgeries that you were 10 trained in? 11 A The additional surgeries I was trained 12 in at LSU were mostly complex fistula repairs, 13 because the person that I -- that was the head 14 of that program was an internationally-known 15 expert on fistulas. 16 Q And synthetic slings were not around at 17 the time of your fellowships, correct? You 18 didn't learn that until afterwards? 19 A I don't know that they were around. I 20 don't -- the -- I remember us discussing -- as a 21 fellow and then after my fellowship discussing 22 the use of synthetic meshes as a sling and it 23 seemed like an incredibly outrageous idea at the 24 time.</p>

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<p>1 Q It was definitely a new mind set at the</p> <p>2 time in how to go about treating SUI in women?</p> <p>3 A Correct.</p> <p>4 Q So you are board certified in OB/GYN,</p> <p>5 correct?</p> <p>6 A Correct.</p> <p>7 Q And you've also sat for the Female</p> <p>8 Pelvic Medicine and Reconstructive Surgery</p> <p>9 Boards?</p> <p>10 A I did.</p> <p>11 Q And that was in 2013 that you were</p> <p>12 board certified in that?</p> <p>13 A I believe that's correct.</p> <p>14 Q You're not board certified in urology,</p> <p>15 correct?</p> <p>16 A Correct.</p> <p>17 Q Can you take me through the chronology</p> <p>18 of your private practice. Where did you start</p> <p>19 your private practice?</p> <p>20 A I've never been in private practice.</p> <p>21 Q So you've just been affiliated with --</p> <p>22 how would you describe your practice, then?</p> <p>23 A I've been an employed physician my</p> <p>24 entire life.</p>	<p>1 I've never had to hire office managers</p> <p>2 or look for office space or worry about whether</p> <p>3 a bill's coming in to pay electricity. I show</p> <p>4 up and do the job that I am requested based on</p> <p>5 my contract with my employer and I fulfill the</p> <p>6 duties of my -- my job.</p> <p>7 Q I see. So rather than having what we</p> <p>8 would consider like a doctor's office practice</p> <p>9 type thing, you work for the hospitals that</p> <p>10 you've been employed for?</p> <p>11 A Yes, ma'am.</p> <p>12 Q How many patients would you see in a</p> <p>13 given week? How much of your time is dedicated</p> <p>14 to seeing patients as opposed to performing</p> <p>15 surgeries? Let's take now.</p> <p>16 A Well, now is a little different than</p> <p>17 before. Because in 2012, I became a chairman</p> <p>18 and my -- my duties and responsibilities changed</p> <p>19 dramatically at that juncture. Currently, I see</p> <p>20 patients on Mondays and Wednesdays for a full</p> <p>21 day, and I operate on Tuesdays and Thursdays for</p> <p>22 a full day. And on Fridays is a full day</p> <p>23 dedicated to administrative work, which I also</p> <p>24 interject in between cases and patients Monday</p>
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<p>1 Q But you've treated patients in your</p> <p>2 capacity as an employed physician for the</p> <p>3 institutions that are listed in your CV?</p> <p>4 A Yes, ma'am.</p> <p>5 Q How long have you been treating</p> <p>6 patients for prolapse and SUI?</p> <p>7 A I started treating patients two weeks</p> <p>8 after I finished my fellowship in 19 -- July of</p> <p>9 1995.</p> <p>10 Q So it's been 21 years now?</p> <p>11 A I don't like to count.</p> <p>12 Q I don't like it either because it's a</p> <p>13 very similar number to mine.</p> <p>14 A Okay.</p> <p>15 Q When you say that you're an employee as</p> <p>16 opposed to being in private practice, I probably</p> <p>17 should know what this means, but what is the</p> <p>18 distinction in your mind between the two things?</p> <p>19 A I am part of an academic group that's</p> <p>20 employed by a hospital which has</p> <p>21 responsibilities for seeing patients and</p> <p>22 training medical students, residents and</p> <p>23 fellows. That has been my life since I was a</p> <p>24 fellow and since I finished my fellowship.</p>	<p>1 through Thursday.</p> <p>2 Q And how -- for how long has that been</p> <p>3 your schedule?</p> <p>4 A Since July of 2012.</p> <p>5 Q And before that, how often -- what was</p> <p>6 your division of time in terms of what days you</p> <p>7 saw patients and what days you performed</p> <p>8 surgery?</p> <p>9 A Before that, I almost always saw</p> <p>10 patients on Mondays, Wednesdays and Fridays, and</p> <p>11 operated on Tuesdays and Thursdays.</p> <p>12 Q So since 2012, you've basically taken</p> <p>13 on more administrative responsibilities at your</p> <p>14 hospital?</p> <p>15 A Correct.</p> <p>16 Q You have on -- in your CV, in the first</p> <p>17 page of your CV, you have what appear to be</p> <p>18 three academic positions listed. Clinical</p> <p>19 associate professor at Mount Sinai, adjunct</p> <p>20 clinical professor, Ross University School of</p> <p>21 Medicine, and then adjunct clinical associate</p> <p>22 professor at NYIT, College of Osteopathic</p> <p>23 Medicine?</p> <p>24 A Correct.</p>

9 (Pages 30 to 33)

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<p>1 Q And you hold all those positions</p> <p>2 currently?</p> <p>3 A I do.</p> <p>4 Q Who do you teach in those positions?</p> <p>5 A At Mount Sinai, I teach medical</p> <p>6 students, residents and fellows. At Ross, we</p> <p>7 have medical students from Ross that come on to</p> <p>8 the OB/GYN rotation at South Nassau Community</p> <p>9 Hospital, where I'm the chairman, and at New</p> <p>10 York Institute of Technology, the osteopathic</p> <p>11 school, they also have medical students that</p> <p>12 come to rotate at South Nassau.</p> <p>13 Q Have you ever trained any of your</p> <p>14 students, whether fellows or residents, in</p> <p>15 surgery to treat SUI or prolapse?</p> <p>16 A Well, I don't train students</p> <p>17 specifically in -- to do these type of</p> <p>18 treatments. Students are more getting a broader</p> <p>19 experience of the indications and how we treat</p> <p>20 things. It's not like I would spend any time</p> <p>21 trying to teach a medical student how to do a</p> <p>22 prolapse surgery. Residents, I</p> <p>23 will take them through cases and I don't have</p> <p>24 the expectation that they will perform these</p>	<p>1 with almost all of them.</p> <p>2 Q We'll come back to the products in a</p> <p>3 little bit. Am I correct, Dr. Garely, that you</p> <p>4 are not an expert in biomaterials?</p> <p>5 A Well, I'm familiar with biomaterials,</p> <p>6 but I'm not a biomaterial engineer.</p> <p>7 Q Okay. You're not a polymer scientist,</p> <p>8 correct?</p> <p>9 A That is correct.</p> <p>10 Q You're not a trained pathologist,</p> <p>11 correct?</p> <p>12 A That is correct.</p> <p>13 Q And you're not board certified in</p> <p>14 pathology, correct?</p> <p>15 A That is correct.</p> <p>16 Q You're not trained in neuropathology;</p> <p>17 is that correct?</p> <p>18 A That is correct.</p> <p>19 Q And you're not an epidemiologist,</p> <p>20 correct?</p> <p>21 A That is correct.</p> <p>22 Q Have you ever been involved in drafting</p> <p>23 instructions for use for a medical device?</p> <p>24 A When -- I've been involved in advising</p>
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<p>1 procedures, but I do have the expectation that</p> <p>2 they will know how to do them. And then my</p> <p>3 fellows, I train them because I have an</p> <p>4 expectation that they will absolutely be doing</p> <p>5 them.</p> <p>6 Q What types of SUI or prolapse surgeries</p> <p>7 do you train your fellows in?</p> <p>8 A I train them on retropubic</p> <p>9 urethropexies, such as Burch procedures. I</p> <p>10 don't do the MMK anymore, but I tell them how to</p> <p>11 do it. And we train them on how to do slings.</p> <p>12 Q Okay.</p> <p>13 A Also suburethral bulking procedures as</p> <p>14 well.</p> <p>15 Q Which slings do you train your fellows</p> <p>16 in?</p> <p>17 A At this point, we only train them in</p> <p>18 retropubic slings.</p> <p>19 Q Is there a particular brand that you</p> <p>20 use when you train them?</p> <p>21 A I use different brands, depending on</p> <p>22 which hospital I'm operating at. I don't</p> <p>23 usually have too much problem with any of the</p> <p>24 products. They're different, but I can work</p>	<p>1 companies in formulating the instructions for</p> <p>2 use, but I've actually not physically put the</p> <p>3 pencil to the paper and written up those</p> <p>4 instructions myself.</p> <p>5 Q Tell me what you have done in advising</p> <p>6 companies on instructions for use.</p> <p>7 A Well, when I was asked to be an expert</p> <p>8 by Ethicon, back in the late '90s, to come</p> <p>9 on-board and evaluate the TVT sling, I was sent</p> <p>10 as part of a group to Sweden and we learned the</p> <p>11 procedure from the inventors of the TVT</p> <p>12 procedure.</p> <p>13 When we came back to the United States,</p> <p>14 we were intimately involved in formulating the</p> <p>15 IFUs to help instruct and educate physicians in</p> <p>16 the United States on how to use the product.</p> <p>17 Q So that was the TVT Retropubic, the</p> <p>18 original TVT sling?</p> <p>19 A Yes, ma'am.</p> <p>20 Q As best as you can remember, what was</p> <p>21 your involvement with respect to the TVT IFU at</p> <p>22 the time, did you receive a draft of it and</p> <p>23 review it and provide commentary, what did you</p> <p>24 do exactly with respect to the IFU?</p>

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<p style="text-align: right;">Page 38</p> <p>1 A It was almost 20 years ago. I just 2 recall that we would have a lot of meetings with 3 the people who were putting the product out. 4 We -- we did everything from educational 5 preparation, educational materials, to helping 6 design the way that the product looked. 7 We went through different iterations of 8 the needles and the mesh, and we discussed 9 things that belonged in the IFU so that 10 physicians could be properly educated on the use 11 of the product. 12 Q As you sit here today, can you recall 13 actually reviewing draft versions of the IFU and 14 providing feedback on those draft versions? 15 A There were so many papers that we were 16 looking at and formulating that to say that I 17 specifically remember any one of those, I can't 18 get my mind around that, no. 19 Q Dr. Garely, is it fair to say that you 20 do not hold yourself out as an expert in product 21 labeling? 22 A I don't understand the question. 23 Q You don't consider yourself an expert 24 in formulating labels for medical devices and</p>	<p style="text-align: right;">Page 40</p> <p>1 from the companies where they were trying to 2 come up with IFUs and they were talking about 3 the regulatory issues regarding the IFUs, those 4 were the documents that I saw. 5 Q Have you ever reviewed FDA regulations 6 relating to labeling and what needs to go into 7 product instructions for use? 8 A I don't know that I've specifically 9 seen that document. 10 Q Have you ever reviewed the document 11 that is known as the FDA Blue Book Memo on what 12 needs to go into instructions for use? 13 A That one sounds familiar. I just don't 14 recall having -- what I would have read in it. 15 But it does sound familiar. 16 Q It sounds familiar to you, but as you 17 sit here today, you're not sure whether or not 18 you've looked at that particular document? 19 A Correct. 20 Q Have you ever reviewed Ethicon's 21 standard operating procedures regarding what 22 information needs to go into instructions for 23 use? 24 A I don't know if I've looked at that</p>
<p style="text-align: right;">Page 39</p> <p>1 what components those labels need to have? 2 A I guess I'm not familiar with what a 3 label would be. 4 Q Fair point. Am I correct that you 5 don't hold yourself out as an expert of what the 6 requirements of the contents of an instructions 7 for use should be? 8 A Well, I do believe that I'm an expert 9 when it comes to the instructions for use when 10 it applies to products that I'm familiar with, 11 yes. 12 Q Have you reviewed regulatory guidances 13 or regulations that address what the 14 requirements of device labeling are? 15 A Only in documents that I reviewed from 16 internal documents of when companies were 17 writing their IFUs and they had background 18 information to go on, but that would have been 19 the only time that I would have reviewed those 20 documents. 21 Q And what are the documents that you 22 reviewed? 23 A Whatever -- from this case or from the 24 Bard case, when I had the internal documents</p>	<p style="text-align: right;">Page 41</p> <p>1 manual, only what I've seen from the internal 2 documents and discussion of what should be 3 included and excluded from the IFU. 4 Q Okay. As you sit here right now, you 5 can't recall looking at a particular Ethicon 6 labeling standard operating procedure, SOP 7 document, that lays out what needs to be in an 8 instructions for use, correct? 9 A Based on the internal documents that I 10 read, I don't even know if such a thing existed 11 because they were choosing to exclude 12 information that would have helped physicians to 13 use the product better. 14 So if there was some guideline, some 15 guideline that would have told them what to do, 16 I don't know that they followed it. Apparently 17 they just chose indiscriminately to include or 18 exclude information that could have or could not 19 have been helpful to physicians. 20 MS. KABBASH: Move to strike as 21 nonresponsive. 22 BY MS. KABBASH: 23 Q My question, Doctor, is as you sit here 24 today, am I correct that you do not recall</p>

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<p>1 reviewing a particular Ethicon standard</p> <p>2 operating procedure document related to what</p> <p>3 should go in labeling?</p> <p>4 A I don't recall.</p> <p>5 Q Am I correct that you are not an expert</p> <p>6 in design control procedures and requirements</p> <p>7 for bringing a product through development?</p> <p>8 A I don't know what you mean by "design</p> <p>9 control."</p> <p>10 Q So there are various FDA regulations</p> <p>11 and requirements that govern a company's process</p> <p>12 of bringing a product through the design stages,</p> <p>13 and eventually to market, they're called design</p> <p>14 controls. And are you familiar with FDA</p> <p>15 regulations that govern what a company must</p> <p>16 accomplish in their design controls?</p> <p>17 A Only from my participation in products</p> <p>18 coming from the drawing board to marketing.</p> <p>19 That's my only experience with that.</p> <p>20 Q And you would not hold yourself out as</p> <p>21 an expert in FDA regulations on design controls,</p> <p>22 correct?</p> <p>23 A That would be correct.</p> <p>24 Q You would not be able to speak to how,</p>	<p>1 A That would be correct.</p> <p>2 Q So that issue would relate to what a</p> <p>3 company must do to get FDA permission to market</p> <p>4 a product in the United States, correct?</p> <p>5 A More or less, correct.</p> <p>6 Q But that does not relate to what steps</p> <p>7 a company has to take internally in order to</p> <p>8 meet its various design control obligations,</p> <p>9 correct?</p> <p>10 A To some degree, it does.</p> <p>11 Q Have you ever worked in the R&D</p> <p>12 department of a medical device company?</p> <p>13 A As an employee or as a consultant?</p> <p>14 Q As an employee.</p> <p>15 A No.</p> <p>16 Q Have you ever advised the FDA on issues</p> <p>17 related to medical devices to treat pelvic organ</p> <p>18 prolapse or FUI?</p> <p>19 A I have not.</p> <p>20 Q So I take you have never testified in</p> <p>21 front of the FDA on those subjects?</p> <p>22 A I have not.</p> <p>23 Q Have you ever assisted any medical</p> <p>24 device company in completing their risk</p>
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<p>1 if at all, design control requirements have</p> <p>2 changed over the past 15 or 20 years?</p> <p>3 A I'm sorry, could you please repeat the</p> <p>4 question?</p> <p>5 Q Sure. You would not be able to comment</p> <p>6 on how design control requirements have changed</p> <p>7 over the past 15 or 20 years?</p> <p>8 A I can comment.</p> <p>9 Q Okay. What -- what is your basic</p> <p>10 knowledge about that?</p> <p>11 A Well, specifically related to pelvic</p> <p>12 floor products, I know that the -- in the past,</p> <p>13 the ability to get a product to market was based</p> <p>14 on approval of similar products. And I know</p> <p>15 that the FDA has changed its approach to a lot</p> <p>16 of these products in that they've looked more</p> <p>17 closely at what is coming on and whether there</p> <p>18 really is true similarity to previous products.</p> <p>19 And they have been more stringent in the</p> <p>20 requirements of premarket testing to show that</p> <p>21 the procedures and the devices are safer.</p> <p>22 Q You're referring to the FDA's recent</p> <p>23 orders to up-classify pelvic floor kits from</p> <p>24 class 2 to class 3?</p>	<p>1 assessments or -- are you familiar with what an</p> <p>2 FMEA or a DDSA is; do you know what those</p> <p>3 documents are?</p> <p>4 A I'm not good on the acronyms. Could</p> <p>5 you tell me what they stand for?</p> <p>6 Q I will try. Design Device Safety</p> <p>7 Assessment. I need to remind myself what an</p> <p>8 FMEA is, Failure Mode Effects Analysis. Are you</p> <p>9 familiar with what those documents are and what</p> <p>10 purpose they serve within a company's design</p> <p>11 control processes?</p> <p>12 A I do and I am.</p> <p>13 Q Have you had involvement in the</p> <p>14 preparation of those documents?</p> <p>15 A I believe that I was involved in the</p> <p>16 preparation of those documents for a device.</p> <p>17 Q Which device was that?</p> <p>18 A I think I was involved in that for the</p> <p>19 device of ligature made by -- at the time I</p> <p>20 think it was U.S. Surgical and I think it was</p> <p>21 acquired or changed its name to Covidien.</p> <p>22 Q And what type of device is that?</p> <p>23 A It's a device that -- it grabs tissue,</p> <p>24 it seals the tissue with heat, and then it cuts</p>

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<p style="text-align: right;">Page 46</p> <p>1 the tissue between the jaws of the grabber. And</p> <p>2 so it can -- it can clamp, cauterize and cut</p> <p>3 tissue. So instead of putting clamps and using</p> <p>4 sutures and scissors, it's a one -- one device.</p> <p>5 Q So what was your role with respect to</p> <p>6 the -- was there an FMEA for that device; is</p> <p>7 that what you're referring to?</p> <p>8 A Correct.</p> <p>9 Q What was your role with respect to that</p> <p>10 FMEA?</p> <p>11 A I was traveling up to Connecticut where</p> <p>12 their research lab was with the veterinarians</p> <p>13 and working on the animal labs on a regular</p> <p>14 basis from New York. I was traveling. And then</p> <p>15 when they moved to Boulder, I was flying out to</p> <p>16 Boulder, and working with them on -- in the</p> <p>17 animal labs in looking at the data to see</p> <p>18 whether the device was safe on certain vessel</p> <p>19 sizes.</p> <p>20 Q And were you actually participating in</p> <p>21 the generation of the FMEA and the putting the</p> <p>22 information in it that was needed to complete</p> <p>23 the FMEA?</p> <p>24 A The veterinarians were doing that. I</p>	<p style="text-align: right;">Page 48</p> <p>1 A Do you want the names of the procedures</p> <p>2 or you want me to describe the operations?</p> <p>3 Q Why don't you tell me the names of the</p> <p>4 procedures that you've done and we'll take it</p> <p>5 from there.</p> <p>6 A Vaginal approach would be anterior</p> <p>7 vaginal repairs, posterior vaginal repairs.</p> <p>8 Sacrospinous ligament fixations, uterosacral</p> <p>9 ligament suspensions. The IVS Tunneller. There</p> <p>10 was an operation that I had developed on my own</p> <p>11 that was presented at the American</p> <p>12 Urogynecologic Society that I had developed in</p> <p>13 conjunction with Boston Scientific where we were</p> <p>14 taking a piece of mesh and we were stitching it</p> <p>15 with a Capio device to the sacrospinous</p> <p>16 ligaments on both sides and then anchoring the</p> <p>17 vaginal apex to the mesh. It didn't really have</p> <p>18 a name. We had a name we called -- just in</p> <p>19 reference, we called it the Garelypexy just</p> <p>20 because I had developed it, but it had not</p> <p>21 really gone any further because we had a lot of</p> <p>22 complications with that procedure.</p> <p>23 Q That was a vaginal procedure?</p> <p>24 A That was a vaginal procedure. And then</p>
<p style="text-align: right;">Page 47</p> <p>1 was -- I guess I was a consultant to them.</p> <p>2 Q Were you aware at that time of what the</p> <p>3 requirements were that needed to go into the</p> <p>4 FMEA for that device?</p> <p>5 A Not specifically, no.</p> <p>6 Q As you sit here today, are you familiar</p> <p>7 with what type of information needs to go into</p> <p>8 an FMEA?</p> <p>9 A At the time, I may have been familiar;</p> <p>10 but I don't recall at this point.</p> <p>11 Q And that's the only -- is that the only</p> <p>12 product where you can recall providing feedback</p> <p>13 that would have fed the FMEA process?</p> <p>14 A I don't know whether or not I was</p> <p>15 involved with the IVS Tunneller at an earlier</p> <p>16 stage when they were formulating that</p> <p>17 information as well because I was doing animal</p> <p>18 labs or cadaver labs with them as well. I just</p> <p>19 don't recall.</p> <p>20 Q Doctor, can you describe for me the</p> <p>21 procedures that you have used to treat prolapse</p> <p>22 in women?</p> <p>23 A Yes.</p> <p>24 Q Go right ahead.</p>	<p style="text-align: right;">Page 49</p> <p>1 I did paravaginal repair anchoring of the</p> <p>2 vaginal apex.</p> <p>3 Q And abdominal -- oh, you're telling me</p> <p>4 only vaginal approaches.</p> <p>5 A I'm still trying to think to see if</p> <p>6 there were any other vaginal approach operations</p> <p>7 that I had either done or attempted.</p> <p>8 I had used biologic graft augmentation</p> <p>9 in the vagina on multiple occasions. I think</p> <p>10 that is it for vaginal; if I think of others,</p> <p>11 I'll let you know.</p> <p>12 Q How about abdominal approach?</p> <p>13 A Abdominal approach would be uterosacral</p> <p>14 ligament suspensions. Abdominal</p> <p>15 sacrocolpopexies. For vaginal, I remember I did</p> <p>16 Manchester procedures.</p> <p>17 Q What's that?</p> <p>18 A A Manchester is where you amputate the</p> <p>19 cervix and you get the uterosacral -- the</p> <p>20 uterosacral ligaments from intraabdominal</p> <p>21 through an incision in the vagina and you bring</p> <p>22 the uterosacral ligaments over the top of the</p> <p>23 cervix. You shorten them. And so it's a</p> <p>24 procedure where you leave the uterus in to fix</p>

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<p>1 the prolapse.</p> <p>2 It's not a very elegant operation and</p> <p>3 the success rates were not very good.</p> <p>4 Q How many times have you used biologic</p> <p>5 grafts to treat prolapse?</p> <p>6 A Innumerable, I could not venture a</p> <p>7 guess. I used them for probably two or three</p> <p>8 years on multiple cases.</p> <p>9 Q Do you still use them today?</p> <p>10 A Not as a -- not as a material to -- for</p> <p>11 prolapse. I use them for -- to help with</p> <p>12 healing.</p> <p>13 Q Which biologic grafts have you used?</p> <p>14 A I used -- what was the name of that</p> <p>15 one. It encapsulated -- it was like a porcine</p> <p>16 dermis. It was --</p> <p>17 MR. MATTHEWS: Who made it?</p> <p>18 THE WITNESS: I think it was made by</p> <p>19 Bard.</p> <p>20 MR. MATTHEWS: Pelvicol?</p> <p>21 A Pelvicol, thank you. I used Pelvicol a</p> <p>22 lot. I used Surgisis. There were -- there were</p> <p>23 a few others. I just don't remember. It's been</p> <p>24 such a long time since I've used biologics, it's</p>	<p>1 Q So you use the biologics to help</p> <p>2 restore the vaginal wall, essentially, where</p> <p>3 there's been a lot of surgery?</p> <p>4 A Correct.</p> <p>5 Q Why did you stop using biologic grafts</p> <p>6 to treat prolapse?</p> <p>7 A For a few reasons. The first reason</p> <p>8 was is that I don't think that the repairs were</p> <p>9 holding. They weren't -- if I was using the</p> <p>10 graft abdominally, the recurrence rates were</p> <p>11 extraordinarily high. If I used it vaginally,</p> <p>12 the recurrence rates were extraordinarily high.</p> <p>13 And the problem with the Pelvicol was that it</p> <p>14 encapsulated, it made the tissue very hard and</p> <p>15 firm, and it wasn't a very realistic repair.</p> <p>16 Patients complained when they had sex.</p> <p>17 Q So is it fair to say that at least for</p> <p>18 the past ten years, biologics have not really</p> <p>19 been a part of the tool chest that you use to</p> <p>20 treat women's prolapse?</p> <p>21 A I would say for at least ten years,</p> <p>22 yes.</p> <p>23 Q Possibly more?</p> <p>24 A Possibly more.</p>
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<p>1 just not in my memory.</p> <p>2 Q How long ago did you stop using</p> <p>3 biologics?</p> <p>4 A For prolapse, probably maybe 12 -- ten</p> <p>5 years, 12 years ago. I use biologics on a</p> <p>6 regular basis for healing still, but not for</p> <p>7 prolapse support.</p> <p>8 Q And what do you mean when you say that</p> <p>9 you use it for healing?</p> <p>10 A When I take out a big piece of mesh and</p> <p>11 there's a large erosion on the vagina and I know</p> <p>12 that I won't have enough vaginal epithelium to</p> <p>13 pull together without causing marked distortion</p> <p>14 of the vagina, I use ACell graft, which is a --</p> <p>15 made from a pig bladder, and it causes</p> <p>16 reepithelialization of the tissue and it heals</p> <p>17 beautifully.</p> <p>18 And so patients who have had -- I would</p> <p>19 say radiation injuries, mesh erosions and</p> <p>20 patients who have had previous surgery where</p> <p>21 somebody was too aggressive and took out a lot</p> <p>22 of the vagina and the patient can't have sexual</p> <p>23 relations, I'll use the ACell as a filler and it</p> <p>24 bridges the gaps and it heals beautifully.</p>	<p>1 Q Can you give me a sense on say for the</p> <p>2 past five to ten years, what has been your</p> <p>3 primary tool chest in order to treat prolapse,</p> <p>4 in other words, do you use certain surgeries in</p> <p>5 certain types of patients, other types of</p> <p>6 surgeries in other types of patients?</p> <p>7 A The answer is yes. And I want to go</p> <p>8 back and add again to the vaginal procedures for</p> <p>9 prolapse. I also use colpocleisis, and I forgot</p> <p>10 to mention that.</p> <p>11 Q And that is when you sew up the vaginal</p> <p>12 opening entirely, correct?</p> <p>13 A It's not sewing the opening, per se,</p> <p>14 it's more like pushing up the prolapse, and it's</p> <p>15 an imbrication technique without removing the</p> <p>16 uterus.</p> <p>17 Q And that basically means -- you do that</p> <p>18 for patients who will not be having sexual</p> <p>19 relations anymore, correct?</p> <p>20 A Correct.</p> <p>21 Q For patients for whom colpocleisis is</p> <p>22 not a realistic option, what are the surgeries</p> <p>23 that you offer currently and say for the past</p> <p>24 five years that you offer to patients who have</p>

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<p>1 prolapse?</p> <p>2 A Abdominal sacrocolpopexy. And</p> <p>3 sacrospinous ligament fixations. That would be</p> <p>4 the bulk of my surgical repertoire for prolapse.</p> <p>5 Q And that's for how many years now would</p> <p>6 you say that's the case?</p> <p>7 A Well, sacrocolpopexies and sacrospinous</p> <p>8 ligament fixations since the time of my</p> <p>9 training.</p> <p>10 Q Do you not offer anterior colpopexies</p> <p>11 and posterior colpopexies in your practice?</p> <p>12 A I -- I'm sorry. I misinterpreted your</p> <p>13 question. I thought you were just referring to</p> <p>14 apical prolapse.</p> <p>15 Q No, with prolapse in general.</p> <p>16 A With prolapse in general, I absolutely</p> <p>17 do have anterior and posterior repairs I would</p> <p>18 say probably to 80 percent of my cases.</p> <p>19 Q What governs whether you choose to do</p> <p>20 an anterior or posterior repair versus an</p> <p>21 abdominal sacrocolpopexy or a sacrospinous</p> <p>22 ligament fixation?</p> <p>23 A It depends on where in the vagina the</p> <p>24 prolapse is located. If it's an anterior wall</p>	<p>1 risk would be injury to the bowel or the urinary</p> <p>2 tract or injury to vessels.</p> <p>3 Q I think you said you've done abdominal</p> <p>4 sacrocolpopexy since your training; is that</p> <p>5 right?</p> <p>6 A That's correct.</p> <p>7 Q And have you -- when you do abdominal</p> <p>8 sacrocolpopexy, do you use a synthetic graft?</p> <p>9 A I do.</p> <p>10 Q What -- did you start out doing open</p> <p>11 abdominal sacrocolpopexy and then transition to</p> <p>12 laparoscopic and robotic?</p> <p>13 A No.</p> <p>14 Q Okay. What have been the types of</p> <p>15 abdominal sacrocolpopexies that you've</p> <p>16 performed?</p> <p>17 A I started with large open incisions on</p> <p>18 sacrocolpopexies, and then through the</p> <p>19 development of my techniques, I'm able to do</p> <p>20 these operations through one five-centimeter</p> <p>21 incision by the pubic bone. And I use</p> <p>22 laparoscopic instruments through a very small</p> <p>23 incision, so I don't need a laparoscope or a</p> <p>24 robot.</p>
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<p>1 defect, then it's fixed with an anterior repair.</p> <p>2 If it's a prolapse -- I'm sorry, if it's a</p> <p>3 posterior wall defect, then it's fixed with a</p> <p>4 posterior repair. And if it's an apical defect,</p> <p>5 then it would be fixed with the sacrospinous</p> <p>6 ligament fixation or a sacrocolpopexy.</p> <p>7 And depending on the presence of one,</p> <p>8 two, three or a combination of any of those</p> <p>9 defects, the patient could end up getting one or</p> <p>10 two or three of those procedures concurrently.</p> <p>11 Q What do you think makes a patient a</p> <p>12 good candidate for an abdominal sacrocolpopexy?</p> <p>13 A Any patient that can medically</p> <p>14 withstand two hours of anesthesia and surgery is</p> <p>15 a good candidate for a sacrocolpopexy, assuming</p> <p>16 that they haven't had so many previous abdominal</p> <p>17 surgeries that it would make the -- the risks of</p> <p>18 the surgery greater than the benefits.</p> <p>19 Q In a patient who's had a lot of</p> <p>20 previous abdominal surgery, why are the risks</p> <p>21 higher for abdominal sacrocolpopexy?</p> <p>22 A It's a relative contraindication. It's</p> <p>23 not absolute and it depends on the types of</p> <p>24 procedures that they've had. But the biggest</p>	<p>1 Q So that's sort of like your own way of</p> <p>2 doing them; is that --</p> <p>3 A It's the way I developed and it's been</p> <p>4 presented and I would say a lot of people have</p> <p>5 adopted this technique.</p> <p>6 Q So the incision -- the five-centimeter</p> <p>7 incision that you use, is that in a sense</p> <p>8 somewhere in between the incision that would be</p> <p>9 required for a laparotomy as opposed -- and the</p> <p>10 type that would be used for laparoscopy, is it</p> <p>11 like a medium-size incision?</p> <p>12 A It's not a medium-size incision, it's a</p> <p>13 very small incision.</p> <p>14 Q Okay.</p> <p>15 A And I developed it because the</p> <p>16 discussion at the time revolving around</p> <p>17 laparoscopic or robotic was for cosmetic</p> <p>18 reasons, and so by making one small incision</p> <p>19 below the hairline, I completely eliminated the</p> <p>20 need for any scarring on the abdomen.</p> <p>21 Q Do you know how many other doctors</p> <p>22 perform abdominal sacrocolpopexy using this</p> <p>23 technique?</p> <p>24 A I don't know the absolute number.</p>

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<p>1 Q Do you have a sense of how many, like</p> <p>2 at least five, at least ten?</p> <p>3 A I would say probably -- I know Roger</p> <p>4 Goldberg in Chicago does the same technique</p> <p>5 because he and I have discussed it multiple</p> <p>6 times. And all the people he's trained, the</p> <p>7 people I've trained, I would say there's</p> <p>8 probably at least 20 people in the country, if</p> <p>9 not more, who are doing this technique.</p> <p>10 It involves making a transverse</p> <p>11 incision on the skin and a vertical incision on</p> <p>12 the fascia. It's called a Kustner incision.</p> <p>13 Q How do you spell that?</p> <p>14 A K-U-S-T-N-E-R.</p> <p>15 Q What grafts have you used in your</p> <p>16 abdominal sacrocolpopexy over time?</p> <p>17 A I've used IntePro. I've used the</p> <p>18 Caldera graft. I've -- I want to preface this</p> <p>19 by saying that I'm not good with remembering all</p> <p>20 of the product names because they come and go so</p> <p>21 frequently that I made a decision 20 years ago</p> <p>22 to just not use up brain space in memorizing all</p> <p>23 the names of the -- and the names are so hard to</p> <p>24 remember, but I can tell you who makes the</p>	<p>1 A Prolene.</p> <p>2 Q Do you still use Prolene today?</p> <p>3 A I do not. Not the brand name Prolene.</p> <p>4 I use Prolene mesh, but not the brand -- I use</p> <p>5 mesh made out of polypropylene. We generically</p> <p>6 refer to polypropylene as Prolene.</p> <p>7 Q Yes, if you don't mind, I'm going to</p> <p>8 try to defend my client's trademarks. So when I</p> <p>9 say "Prolene," just actually this is a good</p> <p>10 clarification for us, when I say "Prolene," I'm</p> <p>11 going to be referring specifically to Ethicon's</p> <p>12 branded Prolene mesh, their polypropylene flat</p> <p>13 meshes. So it's good that we clarify that.</p> <p>14 If I mean polypropylene meshes in</p> <p>15 general, I'll say "polypropylene meshes in</p> <p>16 general."</p> <p>17 A Understood.</p> <p>18 Q What period of time were you performing</p> <p>19 these hundreds of abdominal sacrocolpopexies</p> <p>20 using Prolene?</p> <p>21 A There was no commercially or there were</p> <p>22 no commercially-available Y-meshes for</p> <p>23 sacrocolpopexy until the early 2000s, I think.</p> <p>24 And so from the time I started my fellowship in</p>
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<p>1 products.</p> <p>2 Q Okay.</p> <p>3 A I have used AMS's product, which I</p> <p>4 think is the IntePro. I use Caldera's graft,</p> <p>5 which I don't remember the name of it. There's</p> <p>6 another graft that was made by a group of</p> <p>7 people -- I can't remember the name of the</p> <p>8 company, they worked with Caldera, but I don't</p> <p>9 use their graft because the graft is too flimsy.</p> <p>10 I've used off-the-rack Prolene and cut</p> <p>11 the graft myself. There are probably one or two</p> <p>12 other Y-meshes that's along the line, I tried</p> <p>13 them and didn't like them.</p> <p>14 Q When you say you used off-the-rack</p> <p>15 Prolene, for how many abdominal sacrocolpopexies</p> <p>16 would you have done or did you do with Prolene?</p> <p>17 A Hundreds.</p> <p>18 Q Hundreds?</p> <p>19 A Hundreds.</p> <p>20 Q And was that -- do you know the</p> <p>21 difference between Prolene and Prolene Soft?</p> <p>22 A I do.</p> <p>23 Q Okay. Was it Prolene or Prolene Soft</p> <p>24 that you were using?</p>	<p>1 1993 until probably 2002, and I could be off by</p> <p>2 a few years, but no less than seven years, I</p> <p>3 used off-the-rack Prolene made by the company</p> <p>4 that you're defending.</p> <p>5 Q And did you -- I assume you cut it into</p> <p>6 whatever shape you felt was appropriate for that</p> <p>7 patient?</p> <p>8 A I did. I cut it and I fastened it and</p> <p>9 I made it and I was very proud of my work.</p> <p>10 Q You made it into what you needed it to</p> <p>11 be, right?</p> <p>12 A Yes, ma'am.</p> <p>13 Q Did you ever use Prolene Soft or</p> <p>14 Gynemesh PS for abdominal sacrocolpopexy?</p> <p>15 A I think there was a time, a short time</p> <p>16 when I used the Gynecare Soft. It was the</p> <p>17 softer version. It was a short period of time,</p> <p>18 only a few months when there was a transition</p> <p>19 period between when that came out and when I</p> <p>20 started using commercially-prepared Y kits.</p> <p>21 Q Why did you transition to the Y kits?</p> <p>22 A Because it was more convenient.</p> <p>23 Q They were precut?</p> <p>24 A Yes.</p>

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<p>1 Q The Y kits that you started using, that</p> <p>2 would have been around 2000, 2002, you're</p> <p>3 saying?</p> <p>4 A You have to forgive me. I --</p> <p>5 between -- I got married, I think, in 2002 and</p> <p>6 then my whole life is a blur between my wife and</p> <p>7 my kids and products.</p> <p>8 Q I understand. Were the Y kits that you</p> <p>9 transitioned to, were those meshes made out of</p> <p>10 polypropylene?</p> <p>11 A They were polypropylene.</p> <p>12 Q And I assume at that point in time,</p> <p>13 they were all nonabsorbable polypropylene?</p> <p>14 A Correct.</p> <p>15 Q At any point in time did you transition</p> <p>16 to partially absorbable meshes for your</p> <p>17 abdominal sacrocolpopexies?</p> <p>18 Or not just transition, but more</p> <p>19 broadly, did you ever use partially absorbable</p> <p>20 meshes for your abdominal sacrocolpopexies?</p> <p>21 A I don't believe I ever did.</p> <p>22 Q Did you ever use a mesh -- flat mesh</p> <p>23 called Ultrapro made by Ethicon, which was part</p> <p>24 polypropylene and part absorbable Monocryl</p>	<p>1 BY MS. KABBASH:</p> <p>2 Q Doctor, this is a very short e-mail</p> <p>3 chain. It goes a little bit on to the back, but</p> <p>4 there's nothing really on there other than a</p> <p>5 signature block. And the bottom e-mail is from</p> <p>6 Brian Luscombe to you dated August 13, 2012. Do</p> <p>7 you remember Brian Luscombe at Ethicon?</p> <p>8 A I do.</p> <p>9 Q Have you had recent contact with him?</p> <p>10 A Brian and I were e-mailing probably six</p> <p>11 months ago because we were going to get the old</p> <p>12 group together that brought TVT to market, but I</p> <p>13 was on vacation in Europe, I think, at that</p> <p>14 meeting and so I'm sorry, but I missed it. We</p> <p>15 were going to bring the old band back together.</p> <p>16 Q When you say "the old band," who are</p> <p>17 you referring to?</p> <p>18 A I'm referring to the original group</p> <p>19 that went to Sweden. That would be Nicholas</p> <p>20 Lucente and then Kohli joined afterwards and</p> <p>21 Chip Buttrick. There was probably ten of us.</p> <p>22 Q Were you trained by Professor Uhmston</p> <p>23 there?</p> <p>24 A I was trained by Christian Falconer,</p>
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<p>1 layer?</p> <p>2 A I don't think I ever used the Ultrapro.</p> <p>3 Q Did you ever use a Y-Mesh made by</p> <p>4 Ethicon that came out in about 2012 called</p> <p>5 ARTISYN Y-Mesh?</p> <p>6 A I don't think I used it. I looked at</p> <p>7 it and I think I -- the reason I didn't use it</p> <p>8 was because for me, I need to use a tacker. I</p> <p>9 can't suture the grafts onto the longitudinal</p> <p>10 ligament of the sacrum because my incision is so</p> <p>11 small, and so the first thing I do in the office</p> <p>12 when someone brings me one of these meshes is I</p> <p>13 pull out the tacker and tack it to a -- I have a</p> <p>14 model of a tailbone, and if it looks like the</p> <p>15 mesh won't hold with the tacks, then I don't use</p> <p>16 it.</p> <p>17 So I don't recall. I recall looking at</p> <p>18 the product, I just don't think I've ever used</p> <p>19 it.</p> <p>20 Q Let me show you what I'm marking as</p> <p>21 Exhibit 7.</p> <p>22 (Exhibit Garely 7, E-mail chain Bates</p> <p>23 numbered ETH.MESH.08622118, marked for</p> <p>24 identification.)</p>	<p>1 his partner.</p> <p>2 Q Oh, at Karolinska?</p> <p>3 A Karolinska.</p> <p>4 Q And he was one of the original</p> <p>5 investigators on the Scandinavian multicenter</p> <p>6 trial for DVT, correct?</p> <p>7 A Correct. Do you want me to read this?</p> <p>8 Q You're welcome to take a second to read</p> <p>9 it. I just want to see if it refreshes your</p> <p>10 recollection about your use -- or the extent to</p> <p>11 which you used ARTISYN.</p> <p>12 Let me know when you're ready.</p> <p>13 A Okay.</p> <p>14 Q Does reading this e-mail refresh your</p> <p>15 recollection as to whether you used ARTISYN in</p> <p>16 any number of patients?</p> <p>17 A It doesn't. I don't remember.</p> <p>18 Q It says here, "Brian, thanks for the</p> <p>19 note," or I should say you say at the top,</p> <p>20 "Brian, thanks for the note. I thought the mesh</p> <p>21 was a little stretchy. I also found that the</p> <p>22 attachment point for the Y was hard to see.</p> <p>23 Otherwise, I found the graft to be fine. Let me</p> <p>24 know how you" -- how -- I assume that means "how</p>

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<p>1 I can help you, and I am happy to assist. If</p> <p>2 you have doctors who want to watch the cases,</p> <p>3 get me the contract and I'm good to go." And</p> <p>4 you sign A. Does the last line</p> <p>5 indicate to you that you had some ARTISYN cases</p> <p>6 set up in which you were going to try the mesh</p> <p>7 and you were inviting doctors to come watch</p> <p>8 those cases?</p> <p>9 A No, not necessarily.</p> <p>10 Q What is your understanding of that last</p> <p>11 line?</p> <p>12 A Well, my relationship with the company</p> <p>13 that went back at that point 13 years was that</p> <p>14 when they wanted to send people to watch my</p> <p>15 cases, they had a consulting agreement in place,</p> <p>16 and we were paid by doctor per case. And so it</p> <p>17 was just an extension of the way that we had</p> <p>18 always dealt with each other, which is if you</p> <p>19 wanted to send doctors to train on his</p> <p>20 particular product, then he would have to have a</p> <p>21 consulting agreement in place.</p> <p>22 Q And do you recall whether there was a</p> <p>23 consulting agreement that was entered into at</p> <p>24 this time in 2012?</p>	<p>1 asked.</p> <p>2 Q And you mentioned Caldera's mesh?</p> <p>3 A Yes.</p> <p>4 Q Do you use that today?</p> <p>5 A You mean on a regular basis?</p> <p>6 Q Do you use that currently as one of the</p> <p>7 meshes that is in your tool chest to treat</p> <p>8 prolapse?</p> <p>9 A I do.</p> <p>10 Q Do you have a current go-to in terms of</p> <p>11 your abdominal sacrocolpopexy mesh?</p> <p>12 A I'm pretty flexible. The hospitals --</p> <p>13 I work at three different hospital systems and</p> <p>14 the hospitals have their own deals with the</p> <p>15 companies in terms of getting product based on</p> <p>16 price points. And for me, I have a pretty</p> <p>17 standard mantra with products which is if the</p> <p>18 products are all relatively equal and similar,</p> <p>19 then I would always go for the cheaper product.</p> <p>20 But if the hospitals choose to go with</p> <p>21 a more expensive product as long as it's</p> <p>22 something that I find to be acceptable, then</p> <p>23 it's okay by me, I'll use it.</p> <p>24 Q For the Caldera mesh and the IntePro,</p>
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<p>1 A I don't believe so.</p> <p>2 Q As you sit here -- well, let me ask</p> <p>3 you, did you ever use ARTISYN on a regular</p> <p>4 basis?</p> <p>5 A I don't believe so because I don't -- I</p> <p>6 barely remember -- I don't really remember even</p> <p>7 using the thing, but the fact that I made a</p> <p>8 comment about it indicates that I did use it,</p> <p>9 but I just don't recall.</p> <p>10 Q What meshes have you used for abdominal</p> <p>11 sacrocolpopexy over the past say five to ten</p> <p>12 years?</p> <p>13 A Mostly I used the IntePro and the</p> <p>14 Caldera one.</p> <p>15 Q Is the IntePro -- is the IntePro still</p> <p>16 available today?</p> <p>17 A I used it yesterday.</p> <p>18 Q Is it going to -- I understand that AMS</p> <p>19 is no longer going to be making certain</p> <p>20 products. Do you know if the IntePro is going</p> <p>21 to continue to be available?</p> <p>22 A I do not know.</p> <p>23 Q You haven't been told otherwise?</p> <p>24 A I haven't been told and I haven't</p>	<p>1 are they both fully nonabsorbable or do they</p> <p>2 have partially absorbable components?</p> <p>3 A They are both fully nonabsorbable.</p> <p>4 Q It sounds like you have not regularly</p> <p>5 used a partially absorbable mesh to treat</p> <p>6 prolapse, correct?</p> <p>7 A That's correct, to the best of my</p> <p>8 memory.</p> <p>9 Q When you used Prolene mesh, were you</p> <p>10 aware of what the pore size was of the mesh?</p> <p>11 A Yes.</p> <p>12 Q What is the pore size?</p> <p>13 A Of the IntePro or the Caldera?</p> <p>14 Q No, I'm sorry, I'm talking about the</p> <p>15 Prolene mesh made by Ethicon that you used many</p> <p>16 years ago until the Y-Meshes came out. Did we</p> <p>17 have a miscommunication?</p> <p>18 A No.</p> <p>19 Q Oh, okay.</p> <p>20 A I'm just laughing only because I am</p> <p>21 trying -- I can barely remember what I had for</p> <p>22 dinner last night. I don't recall what the pore</p> <p>23 size was on a mesh that I haven't used in 12</p> <p>24 years.</p>

18 (Pages 66 to 69)

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<p>1 Q Do you recall whether you knew at the</p> <p>2 time what the pore size of the mesh was?</p> <p>3 A I do.</p> <p>4 Q You just don't happen to recall it</p> <p>5 today?</p> <p>6 A That's correct.</p> <p>7 Q Did you -- at the time, whatever the</p> <p>8 pore size was of the Prolene mesh you were</p> <p>9 using, you found that to be appropriate for</p> <p>10 purposes of an abdominal sacrocolpopexy, right?</p> <p>11 A I thought the sacrocolpopexy was the</p> <p>12 best operation for prolapse and I still do.</p> <p>13 Given the materials that I had available to me</p> <p>14 to do the operation, at the time I felt that the</p> <p>15 Prolene mesh was the best material that I could</p> <p>16 get.</p> <p>17 Q And you used it in hundreds of women,</p> <p>18 correct?</p> <p>19 A Hundreds.</p> <p>20 Q Over a thousand, do you think?</p> <p>21 A Over a thousand.</p> <p>22 Q What period of time have you used</p> <p>23 IntePro?</p> <p>24 A From whenever it came out to current.</p>	<p>1 Q Sofradim?</p> <p>2 A Sofradim. And I put that mesh into a</p> <p>3 patient once.</p> <p>4 Q I take it it didn't go very well?</p> <p>5 A It went well. But I developed a -- I</p> <p>6 put the one in and then I wanted to see how the</p> <p>7 patient would do and the patient developed an</p> <p>8 erosion. And I also had used Marlex at some</p> <p>9 point when I was just finishing my fellowship in</p> <p>10 1995, I used Marlex on a few patients and I</p> <p>11 didn't like the way that it healed. It was too</p> <p>12 hard.</p> <p>13 Q Both the IntePro and the Caldera mesh</p> <p>14 are made of polypropylene, correct?</p> <p>15 A Correct.</p> <p>16 Q And is it fair to say that you've used</p> <p>17 IntePro and the Caldera product thousands of</p> <p>18 times?</p> <p>19 A That would be correct.</p> <p>20 Q So between the -- your use of Ethicon's</p> <p>21 Prolene mesh, I think you said some limited use</p> <p>22 of the Prolene Soft mesh, your use of Caldera's</p> <p>23 product and IntePro, fair to say that you have</p> <p>24 implanted a polypropylene graft to treat</p>
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<p>1 Q And what period of time have you used</p> <p>2 the Caldera product?</p> <p>3 A Same thing. From whenever it was</p> <p>4 released to current.</p> <p>5 Q Is there any other abdominal</p> <p>6 sacrocolpopexy mesh that you've used regularly</p> <p>7 that we haven't already talked about?</p> <p>8 A I don't believe so.</p> <p>9 Q Have you ever used mesh or any graft</p> <p>10 for abdominal sacrocolpopexy that was not</p> <p>11 polypropylene?</p> <p>12 A I have.</p> <p>13 Q I think we talked a little bit earlier</p> <p>14 about biologics?</p> <p>15 A True.</p> <p>16 Q All of the meshes that you've used for</p> <p>17 abdominal sacrocolpopexy that were not</p> <p>18 polypropylene, would they all fall into the</p> <p>19 biologic category?</p> <p>20 A No.</p> <p>21 Q What non-biologic products did you use?</p> <p>22 A I used a polyester graft made by a</p> <p>23 company, I think it was Safriderm or Sofra</p> <p>24 something.</p>	<p>1 abdominal sacrocolpopexy in thousands of women,</p> <p>2 correct?</p> <p>3 A That's correct.</p> <p>4 Q And that's going back to your</p> <p>5 fellowship, correct, or even to your residency?</p> <p>6 A Oh, no, I did not use these devices in</p> <p>7 residency.</p> <p>8 Q Okay.</p> <p>9 A Since fellowship, yes. But the</p> <p>10 majority clearly -- my fellowship was two years.</p> <p>11 The majority of these cases were not as a</p> <p>12 trainee, but as an attending physician.</p> <p>13 Q So you clearly believe that</p> <p>14 polypropylene is an appropriate graft to use to</p> <p>15 treat prolapse in an abdominal approach,</p> <p>16 correct?</p> <p>17 A Correct, in an abdominal approach.</p> <p>18 Q Doctor, let me try in a sense to sort</p> <p>19 of cut to the chase on one particular issue. Is</p> <p>20 it your opinion that the polypropylene is fine</p> <p>21 to use to treat prolapse, but it should not be</p> <p>22 used in a transvaginal approach; is that -- if I</p> <p>23 had to kind of boil down your opinion, is that</p> <p>24 what your opinion is?</p>

19 (Pages 70 to 73)

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<p>1 A That's my opinion.</p> <p>2 Q Well, let me kind of get -- we'll get</p> <p>3 more into this later, but you have various</p> <p>4 opinions in your report, Doctor, about</p> <p>5 alternative designs that don't use mesh arms,</p> <p>6 don't use trocars, and you propose some</p> <p>7 alternative materials at one point in your</p> <p>8 report.</p> <p>9 At the end of the day, isn't it correct</p> <p>10 that your opinion is regardless of mesh arms,</p> <p>11 regardless of the use of trocars, regardless of</p> <p>12 pore size, you don't think that mesh should be</p> <p>13 implanted vaginally to treat prolapse; is that</p> <p>14 correct?</p> <p>15 A In its current state, I believe that</p> <p>16 that's correct.</p> <p>17 Q And when you say "in its current</p> <p>18 state," what are you referring to?</p> <p>19 A I'm referring to the fact that in</p> <p>20 medicine, we have research and development and</p> <p>21 new products come along all the time, and I'm</p> <p>22 optimistic and hopeful that we will develop a</p> <p>23 product that can be implanted vaginally, but</p> <p>24 that device does not exist in its current form</p>	<p>1 the surgery unless I knew that they could safely</p> <p>2 withstand two hours of anesthesia.</p> <p>3 I think a patient that has had certain</p> <p>4 types of abdominal-type procedures may not be a</p> <p>5 good risk. For me in my practice and with the</p> <p>6 team that I work with, there are virtually no</p> <p>7 patients that would not be a good candidate for</p> <p>8 the procedure if they needed it.</p> <p>9 Q I think you mentioned -- well, strike</p> <p>10 that.</p> <p>11 Are patients who have an isolated</p> <p>12 cystocele or rectocele and not necessarily an</p> <p>13 apical defect, are they not optimal candidates</p> <p>14 for abdominal sacrocolpopexy?</p> <p>15 A Well, the purpose of the sacrocolpopexy</p> <p>16 would be to address apical prolapse, whether</p> <p>17 it's with a uterus or whether it's without a</p> <p>18 uterus, so if the apex is well supported, the</p> <p>19 patient would probably do well with an isolated</p> <p>20 anterior repair or posterior repair.</p> <p>21 Q So for those patients that abdominal</p> <p>22 sacrocolpopexy would not be the right fit</p> <p>23 necessarily, they should be getting -- you're</p> <p>24 saying they would be better suited for a native</p>
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<p>1 today as we sit here.</p> <p>2 Q Okay. And so that opinion applies not</p> <p>3 only to Ethicon's products, but you're saying</p> <p>4 that you have not seen a transvaginal mesh</p> <p>5 product from any manufacturer to date that you</p> <p>6 believe is appropriate for transvaginal</p> <p>7 implantation to treat prolapse?</p> <p>8 A Some are safer than others, but it</p> <p>9 still wouldn't be my choice.</p> <p>10 Q We'll come back to that in a little</p> <p>11 bit. Are there any particular patients that you</p> <p>12 feel are not good candidates -- we discussed</p> <p>13 this a little bit. Are there patients that you</p> <p>14 feel are not good candidates for abdominal</p> <p>15 sacrocolpopexy?</p> <p>16 A I do.</p> <p>17 Q And can you describe those patients for</p> <p>18 me, again, what categories of patients?</p> <p>19 A Well, patients that won't do well with</p> <p>20 anesthesia for two hours. I'm not saying that</p> <p>21 the operation has to take two hours, but I think</p> <p>22 that two hours is a safe amount of time to</p> <p>23 budget given anything that can happen in an</p> <p>24 operation. So I wouldn't subject a patient to</p>	<p>1 tissue repair as opposed to an abdominal</p> <p>2 sacrocolpopexy because they don't have an apical</p> <p>3 defect?</p> <p>4 A You wouldn't do an operation for a</p> <p>5 problem that doesn't exist. That would be</p> <p>6 wrong.</p> <p>7 Q So you only do abdominal sacrocolpopexy</p> <p>8 where there is an apical defect?</p> <p>9 A There are some instances when I do</p> <p>10 sacrocolpopexies on non-apical defects when</p> <p>11 patients have rectal prolapse, and colorectal</p> <p>12 surgeons oftentimes believe if you stabilize the</p> <p>13 vaginal apex, it will help the patient when they</p> <p>14 repair the rectal prolapse for the indications</p> <p>15 of constipations, that if you stabilize the</p> <p>16 apex, the pressure forces will get transmitted</p> <p>17 better to the rectum, and the patients will have</p> <p>18 an improvement in defecatory function.</p> <p>19 And so in those cases, I do tell the</p> <p>20 patient that this is an operation that's usually</p> <p>21 reserved for prolapse. In your case, you don't</p> <p>22 really have prolapse, but this is why I'm going</p> <p>23 to do the procedure.</p> <p>24 Q But in general, you perform the</p>

20 (Pages 74 to 77)

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<p>1 abdominal sacrocolpopexy on patients with apical 2 defects? 3 A Correct. 4 Q Is the IVS Tunneller the only device 5 that you've ever used to transvaginally treat -- 6 strike that. 7 Is the IVS Tunneller the only synthetic 8 device that you've ever used to treat prolapse 9 transvaginally? 10 A No. 11 Q What others have you used? 12 A The operation that I developed in 13 conjunction with Boston Scientific where we took 14 the Prolene mesh and we anchored it to the 15 sacrospinous ligament bilaterally. 16 Q How many times did you perform that 17 procedure with the Prolene that you were 18 developing with Boston Scientific? 19 A Somewhere between ten and 20. 20 Q And that ultimately did not result in 21 a -- well, were you trying to develop a device? 22 A I was not trying to develop a device. 23 I was trying to develop a technique. 24 Q And that was with Prolene mesh?</p>	<p>1 doing with Boston Scientific? 2 A And the IVS Tunneller. 3 Q So you did use the IVS Tunneller to 4 treat an anterior defect? 5 A Not anterior, you said apical. 6 Q I apologize, I misspoke. Have you ever 7 used transvaginal mesh to treat an anterior 8 defect? 9 A When I used the Prolene mesh on the 10 device with Boston Scientific, we were also 11 using it to treat anterior defects. 12 Q Am I correct that you have never 13 implanted Gynemesh PS transvaginally in any 14 women? 15 A I think you're correct. 16 Q You've never implanted the Prolift, 17 correct? 18 A I've never implanted the Prolift. 19 Q And you've never implanted the 20 Prolift+M, correct? 21 A Correct. 22 Q You've never implanted Bard's Avaulta? 23 A Correct. 24 Q You've never implanted AMS's Elevate?</p>
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<p>1 A It was. 2 Q I apologize. I know you said this, but 3 why is it that you abandoned that procedure? 4 A Because the mesh was eroding at the 5 suture line. 6 Q And you performed -- how many times did 7 you perform the IVS Tunneller procedure? 8 A I think I used it 14 times before I 9 stopped using it, 12 or 14, but over -- it was 10 somewhere in that -- that range. 11 Q And am I right that the IVS Tunneller, 12 you would have used that in the time frame 13 leading up to about 2002? 14 A Somewhere in that neighborhood. 15 Q And is that procedure a posterior and 16 apical procedure? 17 A It is posterior and apical. Some 18 people were using it for anterior as well. 19 Q Did you ever use it for anterior? 20 A I did not. 21 Q Am I correct that you have never used 22 mesh transvaginally to treat an apical defect? 23 A That's not correct. 24 Q That answer related to what you were</p>	<p>1 A Correct. 2 Q You've never implanted Boston 3 Scientific's Uphold? 4 A Correct. 5 Q You've never implanted any transvaginal 6 mesh kit, correct? 7 A Incorrect. 8 Q Other than the IVS Tunneller? 9 A Correct. 10 Q Have you published any studies that 11 address the Prolift+M? 12 A I have not. 13 Q Have you ever served as an investigator 14 in any clinical trial of Prolift+M? 15 A I have not. 16 Q Have you served as an investigator in 17 any clinical trial of Prolift? 18 A No. 19 Q So obviously, Doctor, based on your 20 prior answers to me, you don't have your own 21 body of patients who've had Prolift that you 22 have assessed in followup, correct? 23 A Incorrect. 24 Q Let me be a little more specific. You</p>

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<p>1 don't have any patients in whom you have</p> <p>2 implanted a Prolift that you've had the</p> <p>3 opportunity to follow up postoperatively,</p> <p>4 correct?</p> <p>5 A Correct.</p> <p>6 Q You have treated patients who have had</p> <p>7 a Prolift implanted by other people?</p> <p>8 A Correct.</p> <p>9 Q Am I correct that you've never done a</p> <p>10 study looking at or measuring contraction or</p> <p>11 shrinkage in patients who have undergone</p> <p>12 transvaginal mesh to treat prolapse?</p> <p>13 A Incorrect.</p> <p>14 Q Why is that incorrect?</p> <p>15 A Well, I did an MRI study where we</p> <p>16 looked at sacrocolpopexies in transvaginal mesh</p> <p>17 patients to see whether the vaginal lengths were</p> <p>18 shortened in a short period of time, it was over</p> <p>19 a three-month period of time, so we did look at</p> <p>20 contractions.</p> <p>21 Q And the purpose of that study was to</p> <p>22 assess the total vaginal length?</p> <p>23 A Correct.</p> <p>24 Q In what way in that study did you</p>	<p>1 we were looking to see whether the vaginal vault</p> <p>2 maintained its length, based on these</p> <p>3 procedures.</p> <p>4 Q The published version of your study</p> <p>5 does not report on how many patients experienced</p> <p>6 contraction or shrinkage, correct?</p> <p>7 A Correct.</p> <p>8 Q That was not an endpoint of the study</p> <p>9 either primary or secondary, correct?</p> <p>10 A Correct.</p> <p>11 Q You've never taught any courses or</p> <p>12 given any training on the use of Prolift,</p> <p>13 correct?</p> <p>14 A Not specifically to teach it, but I</p> <p>15 mentioned the Prolift device in lectures.</p> <p>16 Q You've mentioned it in lectures, but</p> <p>17 you've never given any course or training on how</p> <p>18 to appropriately implant it, correct?</p> <p>19 A Correct.</p> <p>20 Q And you've never taught any course or</p> <p>21 professional training on the safe and effective</p> <p>22 use of Prolift+M, correct?</p> <p>23 A Correct.</p> <p>24 Q Have you ever attended any</p>
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<p>1 assess contraction or shrinkage?</p> <p>2 A We used an MRI to do measurements based</p> <p>3 on landmarks of the pelvis.</p> <p>4 Q And in that study, when you -- my</p> <p>5 understanding of that study is that you were</p> <p>6 assessing the success of maintaining -- strike</p> <p>7 that. Let me rephrase this.</p> <p>8 My understanding of that study was that</p> <p>9 you were trying to measure the success of the</p> <p>10 efficacy of the procedure or how well it was</p> <p>11 able to uphold, for lack of a better term; is</p> <p>12 that correct?</p> <p>13 A Well, correct, more or less.</p> <p>14 Q In what way did that study assess</p> <p>15 contraction, what did you do to assess whether a</p> <p>16 patient had experienced contraction?</p> <p>17 A Well, we were just -- it was a -- it</p> <p>18 wasn't specifically to contraction, but it was</p> <p>19 -- we just wanted to see whether there was</p> <p>20 shortening of the vagina, and if there was --</p> <p>21 and we weren't looking to draw conclusions as to</p> <p>22 whether it was a contraction or not.</p> <p>23 We were just looking to see whether or</p> <p>24 not -- a contraction implies a shrinkage, and so</p>	<p>1 Ethicon-sponsored professional education courses</p> <p>2 on Prolift after it was marketed?</p> <p>3 A I wanted to attend one, but the --</p> <p>4 George, the regional rep, told me that unless I</p> <p>5 had promised to line up some Prolift cases, he</p> <p>6 wouldn't sponsor me to go to the course.</p> <p>7 Q That was a rep that you were dealing</p> <p>8 with at the time?</p> <p>9 A He was -- the rep was Tracy. He was</p> <p>10 Tracy's boss. His name was George.</p> <p>11 Q So to date, you have not attended any</p> <p>12 Ethicon professional training courses on</p> <p>13 Prolift, correct?</p> <p>14 A Just what I've seen at my conferences,</p> <p>15 national and international.</p> <p>16 Q But not any Ethicon-sponsored</p> <p>17 professional educational event, correct?</p> <p>18 A They may have sponsored a lunch</p> <p>19 symposium. I don't recall whether it was</p> <p>20 specifically sponsored by them or whether it was</p> <p>21 presented by independent presenters.</p> <p>22 Q And am I correct that you have not</p> <p>23 attended any Ethicon-sponsored professional</p> <p>24 education courses on Prolift+M?</p>

22 (Pages 82 to 85)

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<p>1 A That's correct.</p> <p>2 Q Have you ever looked at a piece of</p> <p>3 Gynemesh PS under the microscope?</p> <p>4 A No.</p> <p>5 Q Have you ever looked at a piece of</p> <p>6 Prolift+M under the microscope?</p> <p>7 A Well, I'd like to just add to that in</p> <p>8 that I've not physically put the mesh under the</p> <p>9 microscope, but I have papers that I have</p> <p>10 reviewed that have pictures of the material</p> <p>11 under the microscope, so I've looked at</p> <p>12 photographs of microscopic material, but I've</p> <p>13 never actually physically taken the mesh and put</p> <p>14 it under the microscope myself.</p> <p>15 Q You've not performed benchtop testing</p> <p>16 on Prolift or Gynemesh PS mesh or tools,</p> <p>17 correct?</p> <p>18 A Correct.</p> <p>19 Q And you've not performed benchtop</p> <p>20 testing on Prolift+M mesh or tools, correct?</p> <p>21 A Correct.</p> <p>22 Q You have not performed animal studies</p> <p>23 on Prolift or Gynemesh PS mesh, correct?</p> <p>24 A Correct.</p>	<p>1 Q At what point in time would it have</p> <p>2 been a deviation from the standard of care, in</p> <p>3 other words, at what point in time did the</p> <p>4 information shift such that you believe it would</p> <p>5 have been a deviation from the standard of care</p> <p>6 to have used it from that point forward?</p> <p>7 A I think that around the time 2007 and</p> <p>8 '8 when the papers started coming out with the</p> <p>9 erosion rates and the dyspareunia rates and the</p> <p>10 pelvic pain issues, that's when I think that --</p> <p>11 when I think surgeons should have started to</p> <p>12 rethink their position on the application of</p> <p>13 this device.</p> <p>14 Q So if a surgeon was using the Prolift</p> <p>15 device in 2009 or '10 or if a surgeon was using</p> <p>16 the Prolift+M device in 2009 or '10, would your</p> <p>17 testimony be that that surgeon deviated from the</p> <p>18 standard of care in using those devices at that</p> <p>19 time?</p> <p>20 A I think it was a deviation from good</p> <p>21 judgment, but I think up until the time when the</p> <p>22 FDA reviewed all the literature and doctors</p> <p>23 relied on reputable sources to advise them, I</p> <p>24 think that up until that time, I think the</p>
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<p>1 Q And you've not performed animal studies</p> <p>2 on Prolift+M mesh, correct?</p> <p>3 A Correct.</p> <p>4 Q Dr. Garely, do you agree that it is not</p> <p>5 a standard -- strike that. Let me start again.</p> <p>6 Do you agree that it would not be a</p> <p>7 deviation from the standard of care for a doctor</p> <p>8 to have utilized Prolift and implanted Prolift</p> <p>9 into women?</p> <p>10 A I'm sorry, could you repeat the</p> <p>11 question?</p> <p>12 Q Sure. Would it have been a deviation</p> <p>13 from the standard of care for a doctor to</p> <p>14 implant Prolift in women, for a trained pelvic</p> <p>15 floor surgeon to implant Prolift in women?</p> <p>16 A Given the information that was</p> <p>17 presented to a surgeon back in the initial time</p> <p>18 of release, I don't think it would have been</p> <p>19 against the standard of care. I think today if</p> <p>20 someone were to implant it, I think it would be</p> <p>21 against the standard of care.</p> <p>22 Q I assume the same answer would apply to</p> <p>23 Prolift+M?</p> <p>24 A Correct.</p>	<p>1 standard of care would still have been met.</p> <p>2 Q Do you need a break?</p> <p>3 A I do.</p> <p>4 MS. KABBASH: Let's take one.</p> <p>5 (Whereupon, a brief recess is taken.)</p> <p>6 BY MS. KABBASH:</p> <p>7 Q We are back on the record and had a</p> <p>8 brief break. Dr. Garely, are you ready to</p> <p>9 proceed?</p> <p>10 A I am.</p> <p>11 (Exhibit Garely Garely 8, Printout from</p> <p>12 Alan Garely, M.D.'s website, marked for</p> <p>13 identification.)</p> <p>14 Q I'm handing you what's been marked as</p> <p>15 Exhibit 8. And I will represent to you that as</p> <p>16 you probably recognize it, that's a printout</p> <p>17 from your website, specifically the frequently</p> <p>18 asked questions from your website. Do you</p> <p>19 recognize it to be that?</p> <p>20 A Yeah, I can't read the questions</p> <p>21 because they're dark.</p> <p>22 Q Yeah, I know. And that's unfortunately</p> <p>23 how it printed out from the website. But</p> <p>24 there's one I want to ask you about and what</p>

23 (Pages 86 to 89)

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<p>1 we've done is if you go to the third page of</p> <p>2 this, it's a little bit more clear to read.</p> <p>3 A Okay.</p> <p>4 Q It's on the right. And if you prefer,</p> <p>5 we've actually -- even though it doesn't look</p> <p>6 exactly the way it does on your website, we've</p> <p>7 blown it up on the very last page and that might</p> <p>8 be the easiest to look at.</p> <p>9 One of the frequently asked questions</p> <p>10 that you answer on your website is you have the</p> <p>11 question, "I have heard or read bad things about</p> <p>12 synthetic mesh. Do you use this material?" And</p> <p>13 then you provide a response, correct?</p> <p>14 A Correct.</p> <p>15 Q Okay. And let's go through the</p> <p>16 response a little bit. You indicate, "Yes, most</p> <p>17 mesh used in pelvic reconstructive surgery is</p> <p>18 made of a material called polypropylene. This</p> <p>19 is commonly called Prolene." And then just to</p> <p>20 stop there, when you reference Prolene there,</p> <p>21 you mean polypropylene in a generic way,</p> <p>22 correct?</p> <p>23 A Well, that's why I put it in quotes so</p> <p>24 that there would be no confusion between the</p>	<p>1 apical prolapse than to anterior and posterior</p> <p>2 repairs.</p> <p>3 Q Okay. So you're pointing out here that</p> <p>4 sometimes because of the weakness of a patient's</p> <p>5 tissues, you're relying on the patient's own</p> <p>6 tissues is going to result in a high failure</p> <p>7 rate and sometimes there is a need to look for</p> <p>8 something else, correct?</p> <p>9 A Well, only in certain applications.</p> <p>10 Obviously, I still do native tissue repairs</p> <p>11 because I think that they have -- I don't think</p> <p>12 they have terribly high failure rates. I think</p> <p>13 that they're good operations to apply. I just</p> <p>14 think in this particular section, I was -- I was</p> <p>15 applying this towards apical descent.</p> <p>16 Q Okay. So at least with apical descent,</p> <p>17 your experience has been that native tissue</p> <p>18 repairs of apical descent has resulted in high</p> <p>19 failure rates, correct?</p> <p>20 A Correct.</p> <p>21 Q And that's consistent with what's in</p> <p>22 the medical literature, correct?</p> <p>23 A More or less, yes.</p> <p>24 Q Then you go on to say, "In a quest to</p>
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<p>1 trademark brand name and what we refer to as</p> <p>2 polypropylene.</p> <p>3 Q Okay. It goes on to say, "Pelvic</p> <p>4 prolapse and incontinence is often caused by</p> <p>5 because of a weakness or absence of normal</p> <p>6 muscle and ligaments. To compensate for these</p> <p>7 weaknesses, we need to use materials that can</p> <p>8 reconstruct or recreate the normal anatomy.</p> <p>9 We've tried to do this by using the patient's</p> <p>10 own tissues," and then you say, "unfortunately</p> <p>11 this has resulted in high failure rates." Do</p> <p>12 you see that?</p> <p>13 A I do.</p> <p>14 Q So is that language there essentially</p> <p>15 saying that native tissue repairs, one of the</p> <p>16 downsides of native tissue repairs is that they</p> <p>17 have high failure rates?</p> <p>18 A Well, I was being broad in the</p> <p>19 description. I was just saying that in certain</p> <p>20 applications of native tissue repairs, the</p> <p>21 failure rates would be high. I'm not</p> <p>22 specifically referencing an anterior repair or a</p> <p>23 posterior repair, but more generically, my frame</p> <p>24 of mind when I was writing this applied more to</p>	<p>1 achieve better results" -- strike that.</p> <p>2 But Doctor, you would agree with me</p> <p>3 that even with anterior colporrhaphies and</p> <p>4 posterior colporrhaphies, those procedures,</p> <p>5 there are reported high failure rates of those</p> <p>6 procedures in the medical literature, correct?</p> <p>7 A Well, it depends how you look at the</p> <p>8 application. When people do anterior and</p> <p>9 posterior repairs and they don't address apical</p> <p>10 descent, then the failure rates are very high</p> <p>11 because the wrong operations were done.</p> <p>12 But in cases where the patient will do</p> <p>13 well with an anterior or a posterior repair,</p> <p>14 then native tissue repairs are good</p> <p>15 alternatives, just like in those applications</p> <p>16 you can use other materials that are good</p> <p>17 alternatives than what it is we're talking about</p> <p>18 today, which is the Prolift or the Prolift+M.</p> <p>19 I'm just saying that everything has a</p> <p>20 success and failure rate, but in the right</p> <p>21 application, they're not necessarily bad.</p> <p>22 Q You are noting high failure rates here</p> <p>23 at the very least for native tissue repairs for</p> <p>24 apical prolapse, correct?</p>

24 (Pages 90 to 93)

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<p>1 A More or less, yes.</p> <p>2 Q You indicate here, "In a quest to</p> <p>3 achieve better results, new formulations of</p> <p>4 Prolene have been developed." And you say,</p> <p>5 "This new material is very safe." Do you see</p> <p>6 that?</p> <p>7 A I do.</p> <p>8 Q Which materials are you referring to</p> <p>9 there?</p> <p>10 A I was talking about the lighter weight</p> <p>11 meshes that we were applying for</p> <p>12 sacrocolpopexies and that was what I was --</p> <p>13 because the previous iterations of</p> <p>14 sacrocolpopexy mesh had higher erosion rates.</p> <p>15 So the newer material was much safer.</p> <p>16 Q And you're referring to here -- and the</p> <p>17 materials that you're referring to here would</p> <p>18 include the Caldera product and the IntePro that</p> <p>19 you used?</p> <p>20 A Correct.</p> <p>21 Q And those are polypropylene products,</p> <p>22 correct?</p> <p>23 A Correct.</p> <p>24 Q Do you know what the pore sizes of the</p>	<p>1 A I think I would have had to rethink the</p> <p>2 procedure if the erosion rates were coming in</p> <p>3 much higher.</p> <p>4 Q What are your erosion rates now with</p> <p>5 the Caldera product and the IntePro?</p> <p>6 A Probably around 1 percent.</p> <p>7 Q And that's based on your personal</p> <p>8 experience in your practice, correct?</p> <p>9 A Correct.</p> <p>10 Q When you say -- well, we'll get to that</p> <p>11 in a second because you quote a 1 percent rate</p> <p>12 here. You go on to say a couple of sentences</p> <p>13 down from where we left off, "Research studies</p> <p>14 have shown that mesh placed through the vagina</p> <p>15 to fix vaginal prolapse has a much higher rate</p> <p>16 of complications than mesh applied through an</p> <p>17 abdominal or laparoscopic incision," and then</p> <p>18 you note, "often less than 1 percent." What</p> <p>19 does that 1 percent refer to?</p> <p>20 A It corresponds to reports of mesh</p> <p>21 erosions from people who have done laparoscopic</p> <p>22 or abdominal approach sacrocolpopexies.</p> <p>23 Q Is this -- does the 1 percent represent</p> <p>24 your personal exposure rate in performing</p>
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<p>1 Caldera and IntePro products are?</p> <p>2 A As we sit here today, off the top of my</p> <p>3 head, I don't recall. I looked at those at the</p> <p>4 time when I started using the products, but I</p> <p>5 don't recall exactly right now.</p> <p>6 Q Do you remember if you -- if the pore</p> <p>7 size was ever part of your consideration as to</p> <p>8 whether you would use those products? In other</p> <p>9 words, did you ever say I'm not using those</p> <p>10 products unless they have a pore size of at</p> <p>11 least X?</p> <p>12 A Absolutely.</p> <p>13 Q And so did you look at the pore sizes</p> <p>14 for that purpose?</p> <p>15 A It was one of the things I looked at.</p> <p>16 Q What was your exposure rate when you</p> <p>17 were using the hand-fashioned Prolene for</p> <p>18 abdominal sacrocolpopexy?</p> <p>19 A It was around 3 percent.</p> <p>20 Q That's a relatively low rate, isn't it?</p> <p>21 A I thought it was pretty okay.</p> <p>22 Q Certainly if you had a much higher</p> <p>23 exposure rate, you would not have implanted the</p> <p>24 Prolene in over a thousand women, correct?</p>	<p>1 abdominal sacrocolpopexies?</p> <p>2 A No.</p> <p>3 Q What -- is it -- what is it based on?</p> <p>4 Is it based on the medical literature?</p> <p>5 A Based on the medical literature and</p> <p>6 discussions with surgeons at meetings and what</p> <p>7 people say their erosion rates are.</p> <p>8 Q With respect to the medical literature,</p> <p>9 what studies are you relying on here for the</p> <p>10 fact that -- of a 1 percent erosion rate?</p> <p>11 A Well, there are -- if you -- I said</p> <p>12 often less than 1 percent. I didn't say that</p> <p>13 was the rate. And when I quote patients at the</p> <p>14 time of surgery, I don't talk about what other</p> <p>15 surgeons have. I give them in writing what my</p> <p>16 erosion rates are.</p> <p>17 And I have two erosion rates. I have</p> <p>18 an erosion rate if I do a hysterectomy with</p> <p>19 removal of the cervix, or if I do a suspension,</p> <p>20 when there is a presence of a cervix. So I have</p> <p>21 two separate erosion rates.</p> <p>22 Q In terms of the medical literature,</p> <p>23 what medical literature supports an erosion rate</p> <p>24 of 1 percent for abdominal sacrocolpopexy?</p>

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<p style="text-align: right;">Page 98</p> <p>1 A There have been studies where people</p> <p>2 have published success rates with erosion rates</p> <p>3 in the 1 percent range.</p> <p>4 Q Would you agree the majority of studies</p> <p>5 that look at erosion rates for abdominal</p> <p>6 sacrocolpopexy report erosion rates that are</p> <p>7 higher than 1 percent?</p> <p>8 A Some do, some don't.</p> <p>9 Q Are you familiar with the Nygaard study</p> <p>10 from 2013 on the extended care study patients?</p> <p>11 A I don't recall the study specifically,</p> <p>12 but if you show it to me I would like to review</p> <p>13 it.</p> <p>14 Q Okay. Do you recall as you sit here</p> <p>15 today that the care study reported erosion rates</p> <p>16 well over 1 percent?</p> <p>17 A I do recall that.</p> <p>18 Q And what is the exposure rate that you</p> <p>19 recall the care study reporting?</p> <p>20 A Off the top of my head, I don't recall,</p> <p>21 but I would have to look at the paper, the</p> <p>22 specific number.</p> <p>23 Q As you sit here right now, can you</p> <p>24 point to a particular medical study that</p>	<p style="text-align: right;">Page 100</p> <p>1 world that you're referencing here?</p> <p>2 A When I wrote this, I was mostly</p> <p>3 thinking about Vince Lucente.</p> <p>4 Q And in this sentence, are you</p> <p>5 acknowledging that, you know, there are some</p> <p>6 very highly trained pelvic floor surgeons out</p> <p>7 there who use transvaginal mesh to treat</p> <p>8 prolapse and have great success with it?</p> <p>9 A Well, when you say "success," I look at</p> <p>10 it like do the ends justify the means. Yes,</p> <p>11 they may be successful in treating the problem,</p> <p>12 but that doesn't necessarily eliminate the risks</p> <p>13 that are associated with their success.</p> <p>14 And so if you're asking me -- I'm not</p> <p>15 sure if I understand the question.</p> <p>16 Q Let me reframe the question.</p> <p>17 A Okay.</p> <p>18 Q You're acknowledging in this sentence</p> <p>19 that there are certain fine surgeons in the</p> <p>20 world, including Dr. Lucente, who use</p> <p>21 transvaginal mesh and have low complication</p> <p>22 rates with that use of mesh, correct? That's</p> <p>23 what you say here, right?</p> <p>24 A According to Vince's data, yes, that</p>
<p style="text-align: right;">Page 99</p> <p>1 reported an exposure rate for abdominal</p> <p>2 sacrocolpopexy of less than 1 percent? Can you</p> <p>3 point to one right now?</p> <p>4 A Specifically, no, I would have to look</p> <p>5 at the literature.</p> <p>6 Q Your FAQ response goes on to say, "When</p> <p>7 considering the safety of any mesh product or</p> <p>8 procedure, the skill of the surgeon implanting</p> <p>9 the material is of paramount importance." You</p> <p>10 continue to agree with that today, correct?</p> <p>11 A Absolutely.</p> <p>12 Q And that applies to not just pelvic</p> <p>13 surgery, but any surgery, that the skill of the</p> <p>14 surgeon is something that can have a very</p> <p>15 important impact on the outcome and the success</p> <p>16 of the surgery, correct?</p> <p>17 A Correct.</p> <p>18 Q You go on to say here, "Some of the</p> <p>19 finest surgeons in the world use vaginal" --</p> <p>20 strike that.</p> <p>21 You go on to say, "Some of the finest</p> <p>22 surgeons in the world use vaginally applied mesh</p> <p>23 with low complication rates."</p> <p>24 Who are the finest surgeons in the</p>	<p style="text-align: right;">Page 101</p> <p>1 would -- that would apply to him.</p> <p>2 Q Do you know Dr. Lucente?</p> <p>3 A I do.</p> <p>4 Q Do you regard him highly as a surgeon?</p> <p>5 A I do.</p> <p>6 Q And there are other surgeons beyond</p> <p>7 Dr. Lucente who are well trained and have</p> <p>8 reported positive experience with transvaginal</p> <p>9 mesh with low complication rates, correct? He's</p> <p>10 not the only one, is what I'm saying, correct?</p> <p>11 A That's correct.</p> <p>12 Q On that note, Doctor, let me ask you,</p> <p>13 is it your opinion that even doctors well</p> <p>14 trained like Dr. Lucente and others who have</p> <p>15 used transvaginal mesh and have had low</p> <p>16 complication rates with it, is it your opinion</p> <p>17 that those meshes should not be available to</p> <p>18 them to use?</p> <p>19 A It is my opinion, yes.</p> <p>20 Q Why shouldn't they have the choice of</p> <p>21 this tool to use when they feel that it's</p> <p>22 appropriate?</p> <p>23 A Because they can't pick the patients</p> <p>24 that are going to get complications any better</p>

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<p>1 than anyone else. And when we talk about, yes,</p> <p>2 they can have great results, I just don't think</p> <p>3 that -- that one patient out of 100 who has</p> <p>4 irreparable harm with pain, sexual dysfunction,</p> <p>5 bladder and rectal dysfunction, justifies the</p> <p>6 fact that they may have a good percentage of</p> <p>7 patients that do well.</p> <p>8 I don't -- I don't believe that that is</p> <p>9 good medical judgment. That's why I don't think</p> <p>10 they should have these tools available. They're</p> <p>11 dangerous. And the arms of the particular</p> <p>12 Prolift and the Prolift+M contributed to a lot</p> <p>13 of those problems, and I think there are better</p> <p>14 alternative products than that product.</p> <p>15 Q Doctor, I'm sure you're aware that in</p> <p>16 other parts of our mesh litigation, there are</p> <p>17 plaintiffs' experts who are asserting that the</p> <p>18 TVT slings are dangerous. Are you -- you're</p> <p>19 aware of that, right?</p> <p>20 A I'm aware of that.</p> <p>21 Q You're not one of them today, you</p> <p>22 haven't provided an opinion that the TVT slings</p> <p>23 are defective, right, that's not one of your</p> <p>24 opinions?</p>	<p>1 Q The Prolift -- the FDA actually has not</p> <p>2 said anything specifically about the -- well,</p> <p>3 strike that.</p> <p>4 The FDA has not made any statement that</p> <p>5 the Prolift in particular is dangerous, correct?</p> <p>6 The FDA has put out an order to seek to</p> <p>7 reclassify transvaginal mesh kits, but it has</p> <p>8 not formulated any conclusion as to the safety</p> <p>9 of Prolift in particular, correct?</p> <p>10 MR. MATTHEWS: Objection to the</p> <p>11 compound question.</p> <p>12 BY MS. KABBASH:</p> <p>13 Q Go ahead, you can answer.</p> <p>14 A Without using the word -- they don't</p> <p>15 need to use the word "dangerous." It's implied</p> <p>16 when they say that there's a high risk of, and</p> <p>17 then they list the risks such as pelvic pain,</p> <p>18 dyspareunia, urinary incontinence, urinary</p> <p>19 retention, issues with bowel function, erosions,</p> <p>20 chronic bleeding. I don't need the FDA to use</p> <p>21 the word "dangerous" when they list those</p> <p>22 complications. I think it's implied that they</p> <p>23 are dangerous.</p> <p>24 Q Dr. Garely, am I correct that the FDA</p>
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<p>1 A Correct.</p> <p>2 Q Am I correct that -- we'll talk about</p> <p>3 this more later, but you've used a considerable</p> <p>4 number of the TVT slings, correct?</p> <p>5 A Correct.</p> <p>6 Q You've implanted TVT in its various</p> <p>7 iterations in many women, correct?</p> <p>8 A Correct.</p> <p>9 Q Would it be appropriate for those</p> <p>10 products to be removed as a choice from you to</p> <p>11 treat your patients because plaintiffs' experts</p> <p>12 were alleging that they were dangerous?</p> <p>13 A There's a difference between them</p> <p>14 alleging that it's dangerous and me stating that</p> <p>15 it's dangerous. Prolift and Prolift+M are</p> <p>16 dangerous. TVT slings are not dangerous.</p> <p>17 That's the difference.</p> <p>18 Q You certainly would not want the TVT</p> <p>19 slings taken away from you as an option to treat</p> <p>20 your patients, correct?</p> <p>21 A Because it's not dangerous and the FDA</p> <p>22 has said that it's not dangerous, but the FDA</p> <p>23 has said that the Prolift and the Prolift+M are</p> <p>24 dangerous.</p>	<p>1 has never -- prior to the discontinuation of</p> <p>2 Prolift, the FDA never revoked the 510(k)</p> <p>3 clearance for Prolift, correct?</p> <p>4 A They did not revoke the 510(k)</p> <p>5 clearance, but they came back with additional</p> <p>6 requirements.</p> <p>7 Q And am I also correct that the FDA</p> <p>8 never revoked the 510(k) clearance of Prolift+M,</p> <p>9 correct?</p> <p>10 A Same answer.</p> <p>11 Q Let's talk about slings for a second.</p> <p>12 We've spoken before about the nonsynthetic mesh</p> <p>13 surgeries that you've performed to treat stress</p> <p>14 urinary incontinence. I'm going to ask you</p> <p>15 about some slings and I'd like you to tell me if</p> <p>16 you've used them as best you can.</p> <p>17 You have used the TVT Retropubic,</p> <p>18 correct?</p> <p>19 A Yes.</p> <p>20 Q Do you use it today?</p> <p>21 A Yes.</p> <p>22 Q Have you used it ever since it came out</p> <p>23 on the market in 1998?</p> <p>24 A Yes.</p>

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<p>1 Q So you have used TVT Retropubic for 18</p> <p>2 years, correct?</p> <p>3 A More or less, yes.</p> <p>4 Q Is it fair to say that you have</p> <p>5 implanted -- how many women have you implanted</p> <p>6 with TVT Retropubic?</p> <p>7 A I probably do 120 slings a year, give</p> <p>8 or take, maybe a little less now that I'm doing</p> <p>9 administrative stuff. There was a period of</p> <p>10 time for probably three years where I did --</p> <p>11 majority were transobturator tape slings. So if</p> <p>12 you discount three or four years of TOTs and</p> <p>13 then you subtract down for the last three years,</p> <p>14 I've probably down 80 slings a year instead of</p> <p>15 120.</p> <p>16 So let me see, so that's -- I don't</p> <p>17 know, I'm not any better with all this</p> <p>18 compounded math either, but I would say the</p> <p>19 number is probably going to come in somewhere</p> <p>20 between 1500 and 2,000.</p> <p>21 Q Is that -- is the 1500 to 2,000 number,</p> <p>22 is that -- strike that.</p> <p>23 1500 to 2,000, does that apply to all</p> <p>24 slings that you've done, mesh slings?</p>	<p>1 went back to 120 times '7, '8, '9, '10, '11,</p> <p>2 '12, '13, '14, that's eight years.</p> <p>3 So that's 480 plus 60, plus 0, 6, 1 --</p> <p>4 960, and the last two years, I've probably done</p> <p>5 160. So what's 160 plus 960 plus 60 plus 480?</p> <p>6 That's about right, that's what I said, 1,516,</p> <p>7 1,516 TVTs.</p> <p>8 MS. KABBASH: Let's mark that what you</p> <p>9 just wrote so we can refer to it.</p> <p>10 A Okay.</p> <p>11 (Exhibit Garely 9, Handwritten</p> <p>12 estimation of prior TVT retropubics performed by</p> <p>13 Dr. Garely, marked for identification.)</p> <p>14 MS. KABBASH: So I'm going to mark this</p> <p>15 piece of lined paper in which you've done</p> <p>16 calculations as Exhibit 9, and you have the</p> <p>17 number on here 1,516 TVT.</p> <p>18 BY MS. KABBASH:</p> <p>19 Q And, Doctor, is that your best estimate</p> <p>20 as to how many TVT Retropubic procedures you've</p> <p>21 done?</p> <p>22 A More or less.</p> <p>23 Q If you don't mind, I'm going to write</p> <p>24 the word "retropubic" on here, just to be clear</p>
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<p>1 A No, I'm just talking about the TVTs.</p> <p>2 Q So 1500 to 2,000 TVT slings or slings</p> <p>3 that fall in the TVT family of products?</p> <p>4 A Correct.</p> <p>5 Q Okay. So that would include</p> <p>6 retropubics, correct?</p> <p>7 A Well, I'm talking only retropubic TVTs.</p> <p>8 I'm not talking about a separate category, which</p> <p>9 is TVT-Os or TOTs.</p> <p>10 Q Okay. Thank you, I appreciate it. I</p> <p>11 want to make sure I'm referring to the numbers</p> <p>12 accurately.</p> <p>13 A If you just give me a minute, I'll give</p> <p>14 you a much better number of breakdown.</p> <p>15 Q Do you want to take a short break so</p> <p>16 you can sort of think it through and write down</p> <p>17 the numbers?</p> <p>18 A Well, let's see, from 1998 to probably</p> <p>19 2003 or '2, that was probably four years of 120.</p> <p>20 And then there was a three-year break of</p> <p>21 probably -- I probably did 20, because I was</p> <p>22 doing -- the rest were TOTs. And then I went</p> <p>23 back to TVTs. So that was from -- let's see,</p> <p>24 2000 to 2007. From 2007 to present, to 2012, I</p>	<p>1 that it's retropubic as opposed to another</p> <p>2 approach.</p> <p>3 A Sure.</p> <p>4 Q Doctor, have you performed TVT EXACT?</p> <p>5 A Which one is the EXACT?</p> <p>6 Q The EXACT is the newer iteration of the</p> <p>7 retropubic that came out in 2010 and it has a</p> <p>8 slightly thinner needle.</p> <p>9 A Yes.</p> <p>10 Q When you perform TVT Retropubic today,</p> <p>11 which version are you using? Are you using the</p> <p>12 EXACT or are you using sort of the classic</p> <p>13 original version?</p> <p>14 A Oh, I want to clarify. When you're</p> <p>15 saying "TVT," I lumped all the product -- all</p> <p>16 the different companies into that number.</p> <p>17 Q Ah, I see. Okay. So Exhibit 9</p> <p>18 reflects how many retropubic slings you have</p> <p>19 done, regardless of whether it was TVT or some</p> <p>20 other brand?</p> <p>21 A Correct.</p> <p>22 Q When you wrote "TVT" on here, you were</p> <p>23 using the term generically?</p> <p>24 A Generic.</p>

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<p>1 Q I'm going to change this to say "1516 2 retropubic slings"; is that fair? 3 A That's fair. 4 Q Okay. Of the 1516 retropubic slings, 5 are you able to estimate for me how many of 6 those are TVT brand retropubic slings? 7 A For the first four years, they were 8 exclusively TVT brand; and then after the first 9 four years, I would say probably 5 percent were 10 TVT brand. 11 Q So from say 1998 to about 2002, you 12 used only TVT Retropubic? 13 A Correct. 14 Q And then after 2002, you started 15 opening up your practice to other brands of 16 retropubic slings, correct? 17 A Correct. 18 Q Have you performed -- and just to be 19 clear, when I say "TVT Retropubic," I'm 20 referring to the Ethicon brand of sling. 21 A Okay. 22 Q As opposed to other retropubic slings. 23 A Understood. 24 Q Since 2002, have you continued to use</p>	<p>1 implanted the TVT brand of retropubic sling in 2 hundreds of women? 3 A That would be fair. 4 Q Would it be fair to say you've 5 implanted the TVT brand of retropubic sling in 6 over 1,000 women or is that too much? 7 A Well, I don't know, we can go look at 8 the numbers again. The first four years were 9 like 480. 10 Q I see. 11 A Then you just figure 15 percent of 12 whatever the residual is. 13 Q Is it fair to say that you've implanted 14 the TVT brand of retropubic sling in over 500 15 women, that's fair, right? 16 A That's fair. 17 Q How about the TVT Obturator sling? And 18 if you want, you know, how many -- what is your 19 best estimate of how many TVT Obturator slings 20 you have used? 21 MR. MATTHEWS: Can we call it like -- 22 so that he doesn't start generically messing 23 this up again, the Gynecare TVT-O versus other 24 transobturator or --</p>
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<p>1 the TVT Retropubic sling? 2 A On occasion, yes. 3 Q How often would you say since then 4 you've used TVT Retropubic? 5 A The only hospital that it's available 6 in that I go to since 2002 -- well, from 2002, I 7 was at Winthrop, and we used -- interchangeably, 8 I think I used the TVT brand and non-TVT brand. 9 And I don't know during the 2002 to 2008 what 10 percentage was the TVT brand. 11 And then from 2008 when I went to Mount 12 Sinai, the only hospital that I operated at that 13 had the TVT brand was Mount Sinai Hospital and 14 Good Samaritan Hospital. And so the bulk of my 15 work was being done actually at South Nassau, so 16 probably 15 percent from 2008 to 2016. 17 Somewhere between that, I guess -- yeah, about 18 15 percent. 19 Q So between 2008 and 2016, about 15 20 percent of the slings that -- retropubic slings 21 that you've done have been the TVT brand 22 retropubic sling? 23 A Correct. 24 Q Is it fair to estimate that you have</p>	<p>1 BY MS. KABBASH: 2 Q However best helps you to 3 differentiate. 4 A I probably only used the TVT-O, the 5 branded TVT, probably 50 times. 6 Q Did you use other obturator approach 7 slings? 8 A I did. 9 Q Do you have a sense of how many -- were 10 they -- by the way, strike that. 11 For the retropubic slings, TVT 12 Retropubic obviously is made out of Prolene 13 polypropylene, correct? 14 A Correct. 15 Q Were all the other retropubic slings 16 that you used also made out of polypropylene? 17 A Yes. 18 Q Same for the obturator approaches 19 you've used? 20 A Yes. 21 Q Are you able to estimate how many 22 obturator approach you've -- approach slings 23 you've used in total, other than the obturator 24 -- other than the TVT-O brand?</p>

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<p>1 A Yes.</p> <p>2 Q About how many?</p> <p>3 A So it was probably over a period of</p> <p>4 three years, I probably did 100 TOTs during</p> <p>5 those three years per year, so it was probably</p> <p>6 300. Then I sort of transitioned over. So I</p> <p>7 would say probably somewhere between three and</p> <p>8 400.</p> <p>9 Q So you've used between three and 400</p> <p>10 obturator approach slings of which about 50 were</p> <p>11 the Gynecare TVT-O brand?</p> <p>12 A That was either in addition to or</p> <p>13 including the 50, somewhere around there.</p> <p>14 Q Okay. Did you -- have you moved away</p> <p>15 from obturator or do you continue to use it</p> <p>16 today?</p> <p>17 A I moved completely away from obturator.</p> <p>18 Q So you -- when you do slings, you</p> <p>19 solely do the retropubic approach?</p> <p>20 A Solely.</p> <p>21 Q And what was the reason for that?</p> <p>22 A Because patients were complaining of</p> <p>23 pain under the area where the sling was going</p> <p>24 into the obturator muscle, and patients that</p>	<p>1 A No.</p> <p>2 Q Have you ever used TVT ABBREVO?</p> <p>3 A Yes.</p> <p>4 Q How many times have you used that?</p> <p>5 A Refresh my memory. Was the ABBREVO a</p> <p>6 retropubic sling?</p> <p>7 Q No, ABBREVO is the newer iteration of</p> <p>8 the Obturator, and it's an obturator approach</p> <p>9 sling that has a sling implant, same as TVT-O,</p> <p>10 but it's 12 centimeters long and instead of the</p> <p>11 sling continuing up, there are positioning lines</p> <p>12 which are removed after the implantation.</p> <p>13 A I'm sorry, I got confused between the</p> <p>14 ABBREVO and the EXACT. As I told you earlier, I</p> <p>15 have a hard time remembering all those trade</p> <p>16 names.</p> <p>17 Q No problem.</p> <p>18 A No, I did not ever use that.</p> <p>19 Q Okay. What are the slings that you are</p> <p>20 primarily using today?</p> <p>21 A Today I use standard Gynecare TVT or I</p> <p>22 use the new one, the --</p> <p>23 Q The EXACT?</p> <p>24 A EXACT. I use the Caldera TVT. Oh, and</p>
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<p>1 were having sex were complaining of pain with</p> <p>2 sex. And so I started seeing, in my own</p> <p>3 practice, a lot of patients who were having</p> <p>4 discomfort pain issues and I was not -- and then</p> <p>5 the mesh was contracting in the TOT space, it</p> <p>6 was getting tight.</p> <p>7 So when I put it and it wasn't</p> <p>8 necessarily a tight band, it would contract down</p> <p>9 and turn into a tight band. And that wasn't</p> <p>10 good, so I changed the practice and we stopped</p> <p>11 doing TOTs.</p> <p>12 Q In what time frame was that?</p> <p>13 A I'm going to say somewhere around 2007</p> <p>14 or '8. I mean, it was probably a three-year run</p> <p>15 that I did. I just don't remember the dates.</p> <p>16 Q What were the other obturator mesh</p> <p>17 slings that you used primarily?</p> <p>18 A Primarily, I was using Monarc and I was</p> <p>19 using the Caldera device.</p> <p>20 Q Did you ever use any mini slings?</p> <p>21 A No.</p> <p>22 Q So you've never used TVT Secure?</p> <p>23 A I've never used it.</p> <p>24 Q Okay. You've never used AMS MiniArc?</p>	<p>1 there's another one, another company -- it's</p> <p>2 called T-Sling. I don't know who makes it. I</p> <p>3 can't remember who makes it. I have been using</p> <p>4 T-Sling too occasionally.</p> <p>5 Q Why do you use the TVT brand slings?</p> <p>6 A Because that's what's available on the</p> <p>7 shelf.</p> <p>8 Q And the TVT brand of slings are made of</p> <p>9 Ethicon's Prolene, correct?</p> <p>10 A It's made of polypropylene, correct.</p> <p>11 Q Are you aware of what the pore size of</p> <p>12 the TVT slings are?</p> <p>13 A I used to know, but I don't recall</p> <p>14 right now.</p> <p>15 Q If I said it was 1.3 millimeters, does</p> <p>16 that sound right to you?</p> <p>17 A That sounds right.</p> <p>18 Q Have you taught others how to perform</p> <p>19 the TVT brand -- strike that.</p> <p>20 Have you taught others how to perform</p> <p>21 surgery using the TVT brand of slings?</p> <p>22 A I have.</p> <p>23 Q How many people?</p> <p>24 A Hundreds.</p>

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<p>1 Q And do those hundreds encompass 2 fellows, residents and attendings? 3 A They do. 4 Q Let me ask you more broadly, what types 5 of people have you trained on TVT? 6 A Well, formal training. I mean, we're 7 not talking about academic, we're talking about 8 as a consultant to industry. I used to do big 9 symposiums where there would be hundreds of 10 people in the audience and they would watch 11 videos and we would instruct them on cadavers on 12 how to do these procedures. 13 I guess they would include fellows and 14 attendings. I guess industry wouldn't sponsor 15 residents to go to those. But in the operating 16 room, I've instructed residents and fellows as 17 well as attendings. 18 Q Have you done all of that training in 19 your capacity as a preceptor or consultant to 20 Ethicon? 21 A Not all, some. 22 Q So some of those hundreds of cases you 23 trained as an Ethicon preceptor and others you 24 did outside of that role?</p>	<p>1 (Exhibit Garely Garely 11, Document 2 entitled Position Statement on Mesh Midurethral 3 Slings for Stress Urinary Incontinence, marked 4 for identification.) 5 BY MS. KABBASH: 6 Q I'm going to hand you what's been 7 marked as Exhibit 11. Doctor, do you recognize 8 this statement? 9 A I do. 10 Q This is the Position Statement on Mesh 11 Midurethral Slings for Stress Urinary 12 Incontinence that was put out by two 13 organizations, AUGS and SUFU, correct? 14 A Correct. 15 Q And that was put out in January 2014, 16 correct? 17 A Correct. 18 Q And am I correct that you are currently 19 a member of AUGS? 20 A Yes. 21 Q And in past years, you have served on 22 the board of AUGS, correct? 23 A Correct. 24 Q Are you a member of SUFU?</p>
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<p>1 A That's correct. 2 Q Are you able to estimate how many 3 trainings you gave as an Ethicon preceptor? 4 A In the beginning when we came back from 5 Sweden, we were -- I was single and I was on the 6 road a lot. I don't -- I didn't have anything 7 holding me back from traveling all over the 8 country to do these lectures and to do these 9 meetings. Sometimes I would do two in a 10 weekend. 11 (Exhibit Garely 10, Handwritten notes 12 by Dr. Garely estimating number of TVT-O brand 13 slings and obturator slings that he's performed, 14 marked for identification.) 15 MS. KABBASH: Just so that the record 16 is clear, Exhibit 10 is the lined notebook paper 17 where Dr. Garely has estimated the number of 18 TVT-O brand slings and obturator slings in 19 general that he's done. 20 BY MS. KABBASH: 21 Q Is that correct, Doctor? 22 A Sorry for the messy handwriting, but 23 yes. 24 Q That's quite all right.</p>	<p>1 A I am not. 2 Q At the top, Doctor, under the name of 3 the document, this statement -- and this 4 statement was approved, as it says on the third 5 page, it was approved by the AUGS Board of 6 Directors and the SUFU Board of Directors 7 January 3, 2014, correct? 8 A Correct. 9 Q At the top this statement says, "The 10 polypropylene mesh midurethral sling is the 11 recognized worldwide standard of care for the 12 surgical treatment of stress urinary 13 incontinence. The procedure is safe, effective 14 and has improved the quality of life for 15 millions of women." Do you agree with that 16 statement, Doctor? 17 A I do. 18 Q Look on the next page. In the second 19 page of the paragraph marked number 3, there is 20 -- a little bit more than halfway down the page, 21 there's a sentence that starts, "Full length 22 midurethral." Do you see that? 23 A I do. 24 Q And it says, "Full length midurethral</p>

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<p>1 slings, both retropubic and transobturator, have 2 been extensively studied and are safe and 3 effective relative to other treatment options 4 and remain the leading treatment option and 5 current gold standard for stress incontinence 6 surgery." Do you see that? 7 A I do. 8 Q Do you agree with that statement? 9 A I do not. 10 Q Why don't you agree with that 11 statement? Well, strike that. 12 Before I ask you that question, do you 13 agree with that statement if it were limited to 14 retropubic? 15 A I do. 16 Q You don't agree with that statement as 17 it relates to transobturator? 18 A Correct. 19 Q Is there any other basis for your 20 disagreement with that statement? 21 A No. 22 Q So is it your opinion that 23 transobturator slings are not the gold standard 24 for stress urinary surgery?</p>	<p>1 Gynecare TVT, marked for identification.) 2 BY MS. KABBASH: 3 Q Doctor, would you agree that the FDA 4 has not distinguished between full length 5 obturator slings and full length retropubic 6 slings in finding them to be safe and effective 7 up to one year in their recent statement; the 8 FDA does not make that distinction, correct? 9 A I don't recall that they made a 10 distinction, but I would have to review their 11 statement. 12 Q Doctor, I'm going to show you what's 13 been marked as Exhibit 12. And this document 14 says at the top, Surgeon's Resource Monograph. 15 Do you see that? 16 A I do. 17 Q Do you remember this document? 18 A I do. 19 Q When was the last time that you have 20 seen it? 21 A In the last -- it's bringing back old 22 memories. The last time I saw this was -- 23 Q Has it been years? 24 A It's been years.</p>
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<p>1 A Correct. 2 Q But you believe that retropubic 3 approach slings are the gold standard? 4 A Correct. 5 Q Okay. So to the extent that you don't 6 believe that full length transobturator slings 7 are the gold standard, you would acknowledge 8 that your position on that would be inconsistent 9 with that taken by AUGS and SUFU in this 10 statement, correct? 11 A I'm sorry, could you repeat that? 12 Q Sure. So to the extent that you -- 13 strike that. 14 You do not believe that transobturator 15 full length slings are the gold standard, that 16 position is inconsistent with the position 17 that's taken by AUGS and SUFU in this statement, 18 correct? 19 A I don't believe the transobturator 20 slings are the gold standard. 21 Q Let me mark another document and hand 22 that to you. 23 (Exhibit Garely Garely 12, Document 24 entitled Surgeon's Resource Monograph on</p>	<p>1 Q That's fine. 2 A But I remember it. 3 Q Okay. And in fact, if you look at the 4 fourth page, it says at the top, "Advisory 5 Panel"? 6 A Okay. 7 Q Your name is listed there on the left 8 column? 9 A Yes. 10 Q You're in fact one of the surgeons that 11 played a major role in creating this document, 12 correct? 13 A Correct. 14 Q And this booklet, which is called the 15 Surgeon's Resource Monograph for TVT, this is a 16 booklet of information about the TVT device that 17 Ethicon put out that gathered the experiences of 18 many surgeons who had performed a lot of TVT 19 surgeries, correct? 20 A For the retropubic approach TVT, yes. 21 Q For retropubic, thank you. 22 And am I correct that the purpose of 23 this document was to collect the experiences of 24 surgeons who were experienced with TVT and put</p>

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<p>1 them in a document and disseminate it out to</p> <p>2 other doctors so that they would have the</p> <p>3 benefit of those experts' experiences, correct?</p> <p>4 A Correct.</p> <p>5 Q Do you recall that this was one of the</p> <p>6 materials that was distributed by Ethicon in its</p> <p>7 trainings for TVT?</p> <p>8 A I do.</p> <p>9 Q And did you in fact distribute it to</p> <p>10 other doctors?</p> <p>11 A I don't think I would have ever</p> <p>12 distributed it to any doctors.</p> <p>13 Q But you recall Ethicon distributing it</p> <p>14 in the context of their trainings and</p> <p>15 professional educations for doctors?</p> <p>16 A Yeah, I remember the people would get</p> <p>17 like a binder and there would be all kinds of</p> <p>18 stuff in it, but that wasn't anything I would</p> <p>19 have anything to do with. They would show up</p> <p>20 and it would be there.</p> <p>21 Q But you recall Ethicon actually giving</p> <p>22 it out to doctors at that time?</p> <p>23 A I do.</p> <p>24 Q Did you write any portion of this</p>	<p>1 participated. I can't tell -- there were so</p> <p>2 many events during that time period, I can't</p> <p>3 tell you where it took place. I'm thinking</p> <p>4 somehow maybe it took place in Florida. I don't</p> <p>5 know.</p> <p>6 Q Doctor, do you agree that it is a</p> <p>7 positive thing, a good thing that the company</p> <p>8 put out this monograph and provided it to</p> <p>9 doctors?</p> <p>10 A I do.</p> <p>11 Q It was a good thing that the company</p> <p>12 was sharing the experiences of some of the top</p> <p>13 experts on TVT so that other doctors could have</p> <p>14 the benefit of that information, correct?</p> <p>15 A As long as it was truthful, I thought</p> <p>16 it was a good idea, yes.</p> <p>17 Q And you believed this document to be</p> <p>18 truthful at the time that it was put out,</p> <p>19 correct?</p> <p>20 A I would have to sit down and look</p> <p>21 through it page by page. I don't recall in my</p> <p>22 brain thinking that there was anything in it</p> <p>23 that I disagreed with. I may not have agreed</p> <p>24 with everything in here, but I don't think -- no</p>
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<p>1 document? Do you remember -- let me ask you the</p> <p>2 broader question.</p> <p>3 What was your role with respect to this</p> <p>4 document?</p> <p>5 A When we did this, I'm getting a memory</p> <p>6 that we were in breakout sessions. We all sat</p> <p>7 down, we hashed out each one of these sections.</p> <p>8 I don't recall any particular section that I was</p> <p>9 in when we did this. But I remember -- I</p> <p>10 remember participating in it. I just don't --</p> <p>11 it's...</p> <p>12 Q A long time ago?</p> <p>13 A It was 16 years ago. I just don't</p> <p>14 remember.</p> <p>15 Q Okay. The front page of this document</p> <p>16 references -- it says, "A report on the June</p> <p>17 2000 summit meeting, a 17-surgeon panel</p> <p>18 representing more than 1200 cases." Do you see</p> <p>19 that?</p> <p>20 A I do.</p> <p>21 Q Do you remember attending summit</p> <p>22 meetings where information that was discussed</p> <p>23 that eventually gave rise to this document?</p> <p>24 A Again, vaguely. I know that I</p>	<p>1 one -- we didn't take a vote as to whether</p> <p>2 everybody agreed on every part of this.</p> <p>3 Q Do you agree, Doctor, that assuming</p> <p>4 that the information in here was accurate, that</p> <p>5 it was a responsible step for Ethicon to put out</p> <p>6 a monograph like this to share information with</p> <p>7 doctors?</p> <p>8 A Yes.</p> <p>9 Q I'm going to show you now what I've</p> <p>10 marked as Exhibit 13.</p> <p>11 (Exhibit Garely 13, Document</p> <p>12 entitled Gynecare TVT with abdominal guides,</p> <p>13 Early Clinical Experience, marked for</p> <p>14 identification.)</p> <p>15 BY MS. KABBASH:</p> <p>16 Q And this says at the first page,</p> <p>17 Gynecare TVT with abdominal guides, Early</p> <p>18 Clinical Experience. Do you see that?</p> <p>19 A Yes.</p> <p>20 Q And if you -- by the way, do you</p> <p>21 remember ever using a TVT brand -- Gynecare</p> <p>22 brand TVT that had an abdominal rather than a</p> <p>23 vaginal approach?</p> <p>24 A I do.</p>

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<p>1 Q Do you remember how many of those you</p> <p>2 did?</p> <p>3 A Not very many. I did not like that</p> <p>4 approach at all.</p> <p>5 Q If you look on the acknowledgments</p> <p>6 page, which is the third or fourth page here?</p> <p>7 A Yes.</p> <p>8 Q It says, This paper represents the</p> <p>9 collective experiences of the following</p> <p>10 physicians who participated in this</p> <p>11 postmarketing clinical evaluation of Gynecare</p> <p>12 TVT with abdominal guides. The views expressed</p> <p>13 by these physicians do not necessarily represent</p> <p>14 those of Gynecare," et cetera. And you were</p> <p>15 one of the surgeons who are listed here,</p> <p>16 correct?</p> <p>17 A Correct.</p> <p>18 Q And did you -- and so you used some</p> <p>19 number of Gynecare TVTs in an abdominal approach</p> <p>20 and provided your feedback for the creation of</p> <p>21 this document, correct?</p> <p>22 A That's correct.</p> <p>23 Q And this is also like a monograph-type</p> <p>24 training material that was provided to surgeons,</p>	<p>1 positive thing for Ethicon to do, correct?</p> <p>2 A Well, there were 17 clinical centers.</p> <p>3 I don't know how many of the cases that were</p> <p>4 contributed from those 17 centers were from my</p> <p>5 center.</p> <p>6 Q Okay.</p> <p>7 A My partner at the time, Larry Lind, was</p> <p>8 also in this and so it's possible Larry was</p> <p>9 doing the majority of these and not just me.</p> <p>10 Q But in asking just about the general</p> <p>11 nature of this document, you'd agree that as</p> <p>12 with the TVT Retropubic Surgeon's Resource</p> <p>13 Monograph, that it is a positive thing that</p> <p>14 Ethicon was trying to compile the clinical</p> <p>15 experience of surgeons and to disseminate that</p> <p>16 to other surgeons so that they might have the</p> <p>17 benefit of that information, correct?</p> <p>18 A If it's truthful, correct.</p> <p>19 Q Doctor, you'd agree with me that</p> <p>20 assuming a woman is going to have a surgical</p> <p>21 approach to treat her prolapse, any surgical</p> <p>22 approach that she could have would present</p> <p>23 risks, correct?</p> <p>24 A Correct.</p>
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<p>1 correct?</p> <p>2 A Correct.</p> <p>3 Q Do you remember this actually -- that</p> <p>4 Ethicon actually distributed this to surgeons at</p> <p>5 the time?</p> <p>6 A This one I don't remember.</p> <p>7 Q Okay. But you remember the preparation</p> <p>8 and completion of this document, correct?</p> <p>9 A Vaguely, but I didn't like that</p> <p>10 approach at all, so it's not something that I</p> <p>11 would have participated in after the initial</p> <p>12 group getting together for this.</p> <p>13 Q This monograph for the TVT with</p> <p>14 abdominal guides is a similar type of document</p> <p>15 to the retropubic monograph that we just looked</p> <p>16 at, correct?</p> <p>17 A Correct.</p> <p>18 Q It's intended to collect the clinical</p> <p>19 experience of certain doctors and to disseminate</p> <p>20 that to other doctors so that they may benefit</p> <p>21 from it, correct?</p> <p>22 A Yes, correct.</p> <p>23 Q And again, that is assuming everything</p> <p>24 in there is accurate, that is a good and</p>	<p>1 Q There's no surgical approach that comes</p> <p>2 without risks, unfortunately; is that correct?</p> <p>3 A Unfortunately, correct.</p> <p>4 Q And any one of the surgical approaches</p> <p>5 to treat prolapse can pose serious risks,</p> <p>6 correct?</p> <p>7 A Well, some more than others. They're</p> <p>8 not all created equal.</p> <p>9 Q But all of the surgeries to treat</p> <p>10 prolapse do pose some amount of -- do pose risk</p> <p>11 of serious injury, correct?</p> <p>12 A Given certain circumstances, the answer</p> <p>13 would be correct.</p> <p>14 Q Would you agree with me that when a</p> <p>15 surgeon is considering treatment options for a</p> <p>16 patient, he or she is -- doesn't consider a</p> <p>17 treatment option in a vacuum, rather you have to</p> <p>18 compare the benefits and risks of that treatment</p> <p>19 option against the benefits and risks of the</p> <p>20 other treatment options, correct?</p> <p>21 A Correct.</p> <p>22 Q What are the potential risks associated</p> <p>23 with native tissue repair in a colporrhaphy, for</p> <p>24 example?</p>

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<p style="text-align: right;">Page 134</p> <p>1 A You can have pelvic pain. You can have</p> <p>2 dyspareunia. You can have hemorrhage, hematoma.</p> <p>3 You can have granulation tissue. You can have</p> <p>4 recurrence. You can have fistula formation.</p> <p>5 You can have incontinence.</p> <p>6 Q Is -- I'm sorry. Were you finished</p> <p>7 or --</p> <p>8 Is vaginal shortening or narrowing also</p> <p>9 a possible risk of colporrhaphies?</p> <p>10 A It's a possibility.</p> <p>11 Q Is it also a risk that if a patient</p> <p>12 experiences pelvic pain from a colporrhaphy,</p> <p>13 that that pain could be persistent?</p> <p>14 A Depending on the way that the</p> <p>15 colporrhaphy is carried out, the answer is it's</p> <p>16 possible it could be persistent.</p> <p>17 Q Would you agree, Doctor, that in any</p> <p>18 pelvic floor surgery, there's a risk of pelvic</p> <p>19 pain, correct?</p> <p>20 A There's always a risk. Anything's</p> <p>21 possible.</p> <p>22 Q Whenever -- strike that.</p> <p>23 A risk of any pelvic floor surgery is</p> <p>24 nerve pain, correct, or injury to nerves,</p>	<p style="text-align: right;">Page 136</p> <p>1 A Well, theoretically, if a nerve injury</p> <p>2 occurs, it could be a sensory nerve or it could</p> <p>3 be a motor nerve. Not all nerve injuries would</p> <p>4 be sensory, some could be motor.</p> <p>5 Q But my question is if a nerve injury</p> <p>6 occurs, am I correct that in any surgery to</p> <p>7 treat prolapse, a nerve injury can result in</p> <p>8 chronic pain? Is there any pelvic organ</p> <p>9 prolapse surgery that is immune from that risk?</p> <p>10 A Well, in anterior and posterior</p> <p>11 repairs, chronic pelvic pain just from an</p> <p>12 isolated nerve injury are not very common</p> <p>13 because they're -- you can get pain associated</p> <p>14 if you've taken out too much tissue, but there</p> <p>15 really are not that many sensory nerves on the</p> <p>16 anterior vaginal wall and posterior wall per se.</p> <p>17 Q Is chronic pain -- pelvic pain from</p> <p>18 an -- is chronic pelvic pain from an anterior or</p> <p>19 posterior colporrhaphy -- strike that, let's</p> <p>20 start again.</p> <p>21 Is chronic pelvic pain a risk of an</p> <p>22 anterior colporrhaphy or a posterior</p> <p>23 colporrhaphy for reasons unrelated to nerve</p> <p>24 damage or nerve injury?</p>
<p style="text-align: right;">Page 135</p> <p>1 correct?</p> <p>2 A Well, some operations more than others.</p> <p>3 I mean, that's part of being a surgeon is</p> <p>4 weighing the risks of different operations. If</p> <p>5 you have an operation like Prolift or Prolift+M</p> <p>6 where you know they have arms that are going</p> <p>7 through vital structures in your nerves or blood</p> <p>8 vessels, that operation would put the patient at</p> <p>9 a much higher risk of developing complications</p> <p>10 than something like a native tissue repair,</p> <p>11 which would be an alternative.</p> <p>12 MS. KABBASH: Move to strike as</p> <p>13 non-responsive.</p> <p>14 BY MS. KABBASH:</p> <p>15 Q I'm not asking you relative rates</p> <p>16 between different surgeries right now. The</p> <p>17 question I'm asking is, do you agree that nerve</p> <p>18 injury is a risk of any surgery to treat</p> <p>19 prolapse?</p> <p>20 A Any surgery to treat prolapse, it's</p> <p>21 possible.</p> <p>22 Q And when a nerve injury occurs, that</p> <p>23 can result in a pain that is persistent,</p> <p>24 correct?</p>	<p style="text-align: right;">Page 137</p> <p>1 A In a -- I don't know that I've ever</p> <p>2 seen a patient with chronic pelvic pain from</p> <p>3 nerve injury in an anterior or posterior repair</p> <p>4 that has been carried out in a correct</p> <p>5 anatomical fashion, meaning if I looked at the</p> <p>6 repair and did the repair or postoperatively in</p> <p>7 the office and the patient has normal anatomical</p> <p>8 support and repair without foreshortening of the</p> <p>9 vagina, I don't know that I've ever seen a</p> <p>10 patient with chronic pelvic pain.</p> <p>11 If the patient -- there was an</p> <p>12 anatomical deformity, meaning that the surgeon</p> <p>13 took out too much tissue or pulled muscles</p> <p>14 together in the midline, or did something that</p> <p>15 distorted the normal access and anatomy of the</p> <p>16 vagina, those patients can have chronic pelvic</p> <p>17 pain from nerve issues, yes.</p> <p>18 Q And my question was not necessarily</p> <p>19 limited to nerve issues. Outside of nerve</p> <p>20 issues, are there other ways that an anterior or</p> <p>21 posterior colporrhaphy can result in chronic</p> <p>22 pain to the patient, chronic pelvic pain?</p> <p>23 A Aside from what I just mentioned?</p> <p>24 Q Yes.</p>

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<p style="text-align: right;">Page 138</p> <p>1 A I don't know that I can answer that</p> <p>2 question, because if a surgeon does an anterior</p> <p>3 repair or posterior repair the way an anterior</p> <p>4 repair or a posterior repair is supposed to be</p> <p>5 done, then there shouldn't be really other ways</p> <p>6 that a patient would experience pain issues.</p> <p>7 If a surgeon didn't know what they were</p> <p>8 doing, and anything's possible, in those</p> <p>9 particular cases, somebody could have other</p> <p>10 issues. I don't know what they would be.</p> <p>11 Q You listed pelvic pain and dyspareunia</p> <p>12 as -- strike that.</p> <p>13 What are the possible risks of</p> <p>14 abdominal sacrocolpopexy?</p> <p>15 A Erosion of mesh is one of them.</p> <p>16 Dyspareunia. Chronic pelvic pain, hemorrhage,</p> <p>17 hematoma, infection. Injury to the bowel,</p> <p>18 injury to the urinary tract. That's most of</p> <p>19 them. I'm sure I can find smaller ones if I</p> <p>20 think harder, but that's the majority.</p> <p>21 Q Is symptoms related to contraction or</p> <p>22 shrinkage also risks of abdominal sacrocolpopexy</p> <p>23 because it involves the mesh implant?</p> <p>24 A Not really.</p>	<p style="text-align: right;">Page 140</p> <p>1 placed transvaginally, where everything sort of</p> <p>2 gets shrinkwrapped around -- circumferentially</p> <p>3 or in one area of the vagina, as opposed to when</p> <p>4 it's placed abdominally, if there's a</p> <p>5 contraction of the mesh because of the --</p> <p>6 because of the distensibility of the vagina and</p> <p>7 the laxity of vaginal tissue, it's imperceptible</p> <p>8 what happens to the vagina secondary to any mesh</p> <p>9 contracture.</p> <p>10 Q So it's your testimony that a</p> <p>11 contraction or shrinkage is not a possible -- or</p> <p>12 is not a potential risk of abdominal</p> <p>13 sacrocolpopexy?</p> <p>14 A Well, I don't know how a contraction of</p> <p>15 the mesh would manifest itself clinically. I'm</p> <p>16 not saying it doesn't happen, I'm just saying if</p> <p>17 you ask me what the risks are, I would never</p> <p>18 tell a patient on a sacrocolpopexy that the risk</p> <p>19 would be contracture of the mesh because that's</p> <p>20 not a clinical finding. I would have to relate</p> <p>21 that to a clinical scenario.</p> <p>22 What would be a clinical scenario with</p> <p>23 mesh contracture from a sacrocolpopexy, I don't</p> <p>24 know. I -- I know that you can get a percentage</p>
<p style="text-align: right;">Page 139</p> <p>1 Q Why is that?</p> <p>2 A Well, because sacrocolpopexy, if</p> <p>3 they're done properly, they don't involve entry</p> <p>4 of the mesh into the vagina. They're placed</p> <p>5 abdominally, there's no splitting of the vagina.</p> <p>6 There's relying on full thickness of the vagina.</p> <p>7 Most -- because of the access, the way</p> <p>8 that the vagina gets pulled upward, you don't</p> <p>9 usually get a constriction of the vagina or a</p> <p>10 narrowing. You get a pull up. It makes the</p> <p>11 vagina longer because of the vector forces that</p> <p>12 are applied on the sacrocolpopexy.</p> <p>13 So I'm sorry, was the question about --</p> <p>14 Q In -- when abdominal sacrocolpopexy is</p> <p>15 done and you use a mesh graft, obviously you're</p> <p>16 relying on tissue integration into that mesh</p> <p>17 graft, correct?</p> <p>18 A To some extent, yes.</p> <p>19 Q You would expect some normal process of</p> <p>20 contraction for wound healing, correct, and</p> <p>21 tissue integration, correct?</p> <p>22 A Well, because it's pulling upward, it</p> <p>23 doesn't -- the contraction doesn't affect the</p> <p>24 vaginal tissue the way it would if it were</p>	<p style="text-align: right;">Page 141</p> <p>1 of patients that can get mesh erosion. Do I</p> <p>2 know that that's related to mesh contracture?</p> <p>3 No, I do not know that.</p> <p>4 Q And is that opinion based on your</p> <p>5 personal experience in what you've seen in your</p> <p>6 practice?</p> <p>7 A And review of the literature. I don't</p> <p>8 recall reading in the literature that there were</p> <p>9 mesh contracture that contributes to a clinical</p> <p>10 scenario.</p> <p>11 Q Doctor, are you able to identify</p> <p>12 specific meshes that you have explanted?</p> <p>13 A I am.</p> <p>14 Q Let me ask you first about Prolift and</p> <p>15 Prolift+M. Have you -- let's start with</p> <p>16 Prolift. Have you explanted meshes that you</p> <p>17 have known to be Prolift or Gynemesh PS?</p> <p>18 A Yes.</p> <p>19 Q And how do you know that they are</p> <p>20 Prolift or Gynemesh PS?</p> <p>21 A I base it on a few factors. One is</p> <p>22 where the patient had their surgery and who the</p> <p>23 surgeon was. Two is the patient telling me what</p> <p>24 the procedure was. Three would be looking at</p>

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<p>1 the operative report. Four would be explanting</p> <p>2 the material and looking at it.</p> <p>3 Q Are you able to tell by looking at</p> <p>4 Prolift that it's Prolift? Do you recognize it</p> <p>5 when you explant it?</p> <p>6 A I usually do.</p> <p>7 Q How do you recognize it?</p> <p>8 A Because the blue lines in the white</p> <p>9 mesh.</p> <p>10 Q Are you able to tell when you explant</p> <p>11 it whether it's Prolift or Prolift+M?</p> <p>12 A I've tried to distinguish between the</p> <p>13 two. I don't know that -- given the way that</p> <p>14 the meshes are explanted, sometimes it's very</p> <p>15 difficult.</p> <p>16 Q How many meshes have you explanted that</p> <p>17 you have known to be either Prolift or</p> <p>18 Prolift+M?</p> <p>19 A Somewhere between 10 and 20 for sure.</p> <p>20 Over that, I don't know for sure.</p> <p>21 Q Does your office have some method of</p> <p>22 tracking what mesh is explanted in any way other</p> <p>23 than what you described to me already? Do you</p> <p>24 document that in some way when you explant a</p>	<p>1 A No, I don't do pathological analysis.</p> <p>2 Q You're not trained for that, correct?</p> <p>3 A I'm not trained for that. In addition,</p> <p>4 the pathologist usually just documents what it</p> <p>5 is I've explanted in terms of foreign material</p> <p>6 mesh and then they'll talk about inflammation</p> <p>7 and whatever else is -- attached to the mesh.</p> <p>8 It's not like I'm looking for them to give me a</p> <p>9 diagnosis of cancer or anything.</p> <p>10 Q Are you able to tell from when you're</p> <p>11 doing the explant, whether the mesh was</p> <p>12 implanted via a vaginal route versus an</p> <p>13 abdominal route?</p> <p>14 A Absolutely.</p> <p>15 Q And in what way can you tell that?</p> <p>16 A Because vaginal applied mesh is almost</p> <p>17 always just at the apex, and transvaginal mesh,</p> <p>18 applied mesh, is almost always on the anterior</p> <p>19 wall, apex or posterior wall. It has to do with</p> <p>20 the anatomic location of where the mesh is</p> <p>21 explanted.</p> <p>22 The difference is also with Prolift and</p> <p>23 Prolift+M, because of the arms and contracture</p> <p>24 and shrinkage of the mesh, I can almost always</p>
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<p>1 mesh and identify what type of mesh it is?</p> <p>2 A I don't specifically document the brand</p> <p>3 name of the mesh, no.</p> <p>4 Q For the -- and am I correct that for</p> <p>5 the 10 to 20 mesh explants that you're referring</p> <p>6 to, you would not be able to distinguish whether</p> <p>7 they are Prolift versus Prolift+M, correct?</p> <p>8 A Only based on the patient's operative</p> <p>9 report or in discussion with their surgeon.</p> <p>10 Q So if you did not find out about it</p> <p>11 through the patient's surgeon or the patient</p> <p>12 telling you what procedure they had, you would</p> <p>13 not be able to know by looking at it whether it</p> <p>14 was a Prolift or Prolift+M?</p> <p>15 A I think it's hard for me.</p> <p>16 Q For any of those explants, did you ever</p> <p>17 view any of them under the microscope?</p> <p>18 A No.</p> <p>19 Q Would it have been your practice to</p> <p>20 send those explants to pathology?</p> <p>21 A A hundred percent.</p> <p>22 Q Okay. Is it fair to say that you would</p> <p>23 not have performed a pathological analysis of</p> <p>24 those explants, correct?</p>	<p>1 feel the entry points of the mesh into the</p> <p>2 pelvis, which is different than you would get on</p> <p>3 an abdominally approached mesh, because</p> <p>4 abdominally placed mesh doesn't use arms.</p> <p>5 Q Have any of the patients for whom</p> <p>6 you've explanted mesh been sent to you by</p> <p>7 attorneys?</p> <p>8 I really should say, have any of the</p> <p>9 patients for whom you've explanted mesh been</p> <p>10 sent to you by the patient's attorney?</p> <p>11 A I don't recall ever getting a patient</p> <p>12 sent to me by an attorney for that purpose. I</p> <p>13 have had patients sent to me by attorneys for</p> <p>14 other reasons, but not for -- I don't think I've</p> <p>15 ever had anybody from a mesh case.</p> <p>16 There was -- there was some firm that</p> <p>17 was trying to see if we would do explants on</p> <p>18 patients with mesh, that they were going to do</p> <p>19 this weird medical funding thing, but it didn't</p> <p>20 pass the sniff test at my hospital so we didn't</p> <p>21 allow it.</p> <p>22 Q You received outreach from a law firm</p> <p>23 like that?</p> <p>24 A I can't remember if it was a law firm</p>

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<p>1 or a loaning guy, a lending guy. There was 2 some -- it was -- it was something about where 3 they were going to give a loan to the patient to 4 pay for the surgery and then we were going to 5 bill the patient and then the patient was going 6 to go to a lawsuit and settle the lawsuit and 7 then the money from their lawsuit was going to 8 come and pay the doctor. And we did not like 9 it. It did not look kosher.</p> <p>10 Q Do you have any record of who that 11 company was?</p> <p>12 A If you made some names, I might 13 remember. I -- I really didn't have any 14 interaction with them. The person at my 15 hospital is the person in charge of physician 16 services, who I trust implicitly, and he was the 17 person who did all the discussions with this 18 guy. And he didn't like it.</p> <p>19 Q If I said the name MedStar Funding, 20 does that sound right?</p> <p>21 A That sounds right.</p> <p>22 Q So you think MedStar Funding is the 23 company that contacted your office for that 24 purpose?</p>	<p>1 A No, I don't believe I've ever seen this 2 before. Well, actually now I'm sort -- I was 3 sort of looking at the pyramid. As I'm reading 4 through these things, I understand what this is 5 about.</p> <p>6 Q And what is your understanding of what 7 this is reflecting?</p> <p>8 A They're saying that -- that the 9 majority of studies are based on background 10 information and expert opinion and they have low 11 quality of evidence. It's sort of a model of 12 what we call evidence-based medicine, and sort 13 of just because I'm the expert and the professor 14 and there's lots of us, we're in every medical 15 school, our opinions are really not worth a lot 16 in the paradigm of evidence-based medicine.</p> <p>17 I'm not saying our opinions are not 18 worth something because there is a whole other 19 school of thought that says that expert opinions 20 do have validity. But if you look at it based 21 on other criteria, they're saying case series 22 are better. Case-controlled studies are better. 23 Cohort studies are better than that.</p> <p>24 And then above that would be randomized</p>
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<p>1 A Correct.</p> <p>2 Q You ultimately declined to do this type 3 of work for MedStar Funding?</p> <p>4 A Absolutely.</p> <p>5 Q How long ago was that?</p> <p>6 A It was when I was at South Nassau, so 7 it must have been somewhere between 2012 and 8 like 2013 or 2014. Somewhere in that range. 9 I'd just left Mount Sinai as a full-time 10 employee and I went to South Nassau as a 11 full-time employee.</p> <p>12 Q I'm going to show you what I've marked 13 as Exhibit 14.</p> <p>14 (Exhibit Garely Garely 14, Document 15 entitled Oxford Levels of Evidence Pyramid for 16 Practitioners, marked for identification.) 17 BY MS. KABBASH:</p> <p>18 Q So you see at the bottom, this is the 19 reference to the Oxford Levels of Evidence 20 Pyramid for Practitioners; do you see that?</p> <p>21 A I do.</p> <p>22 Q Are you familiar with this 23 representation of this pyramid or one that's 24 close to it?</p>	<p>1 controlled trials, and then systematic reviews 2 and then metaanalysis, which looks at multiple 3 studies lumped together.</p> <p>4 Q According to this pyramid, metaanalyses 5 and systematic reviews are considered the 6 highest quality of evidence, correct, followed 7 by randomized controlled trials and others that 8 are listed lower on the page, right?</p> <p>9 A There are, but there's criticism for 10 each one of these.</p> <p>11 Q Do you practice evidence-based 12 medicine?</p> <p>13 A I believe so.</p> <p>14 Q You certainly strive to, correct?</p> <p>15 A I do strive to.</p> <p>16 Q Would you -- do you generally agree 17 with the presentation that's set forth on this 18 pyramid as a general matter? I understand that 19 you can attack a particular study for various 20 reasons, but do you generally agree that 21 metaanalyses and systematic reviews are the 22 highest form of evidence followed by randomized 23 controlled trials?</p> <p>24 A That's accepted, yes.</p>

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<p>1 Q Is there any other way in which the 2 information is presented on this page that you 3 disagree with on a general -- in a general way? 4 A No. 5 Q Where would you consider that animal 6 studies fall in this hierarchy here? They're 7 not really referenced on it. Would animal 8 studies fall below this pyramid? 9 A I -- I don't know where I would put an 10 animal study on this. This is -- I don't know. 11 Q Fair to say that animal studies, while 12 they can be informative and helpful, are not as 13 meaningful to you in assessing the safety of a 14 device as clinical studies are, correct? 15 Clinical studies assessing the use of a device 16 in women? 17 A That would be better. 18 Q Let's take a look at your report. 19 MR. MATTHEWS: Is now a good time to 20 take a break? 21 MS. KABBASH: Yeah, sure. 22 (Whereupon, a brief recess is taken.) 23 BY MS. KABBASH: 24 Q Doctor, am I correct that in the study</p>	<p>1 our fellow, and Sue was our fellow, so the three 2 of them were the fellows, so they would have 3 only participated in whatever Dr. Vardy did. 4 Dr. Gramann never did mesh 5 kits. And Ascher-Walsh, he may have done mesh 6 kits, but I don't know if he ever did the 7 Prolift. I don't know what Chuck did. And then 8 Dr. Condrea -- well, Shimon was our fellow too, 9 so I don't know -- so Shimon didn't do any of 10 the Prolifts. 11 He was a visiting fellow from Israel 12 and he did not have clinical privileges. So 13 Shimon was doing a research fellowship with us, 14 so he only was compiling data. And then 15 Dr. Condrea is a partner of Shimon's in Israel, 16 so I don't think any of the cases were 17 contributed by him. 18 Q You obviously did not do any of the 19 Prolift cases that are reflected in the study, 20 correct? 21 A Obviously. 22 Q Did you do any of the MRI analysis of 23 those Prolift patients? 24 A Well, I -- Jonathan Luchs, the</p>
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<p>1 that you published on the magnetic resonance 2 imaging of abdominal versus vaginal prolapse 3 mesh, am I correct that you found that there was 4 no statistically significant difference in total 5 vaginal length between the abdominal and the 6 vaginal approach? 7 A At three months, yes. 8 Q In that study, you indicate, "In our 9 study, we used Prolift as the vaginal mesh kit 10 because of surgeon preference." Whose 11 preference was that? 12 A Michael Vardy. 13 Q Is he the only doctor in the study who 14 implanted the Prolifts? 15 A I'd have to see the paper. I'll tell 16 you. 17 MS. KABBASH: Actually, we can go ahead 18 and mark it. We'll mark it Exhibit 15. 19 (Exhibit Garely Garely 15, Document 20 entitled Magnetic Resonance Imaging of Abdominal 21 versus Vaginal Prolapse Surgery with Mesh, 22 marked for identification.) 23 A Okay. Azin was our fellow, so she 24 would have done what Dr. Vardy did. Cedric was</p>	<p>1 radiologist, was at my center at Winthrop, where 2 I was based, and I went between Winthrop and 3 Sinai, but I sat with Jonathan and looked at a 4 lot of the images with him, but he did all the 5 interpretations. 6 Q Doctor, if you could turn to your 7 report for Prolift, which is Exhibit 2. And 8 turn to page 6. 9 A Okay. 10 Q Doctor, on page 6 under opinion 2A, you 11 opine that Ethicon brought these products to 12 market without FDA 510(k) clearance, correct? 13 Do you state that opinion there? 14 A I do. 15 Q And by "these products," I understand 16 that you mean the Prolift kits, the different 17 iterations of the Prolift kit? 18 A That's correct. 19 Q Am I correct that you've never worked 20 at the FDA? 21 A That is correct. 22 Q Am I correct that while you may have 23 some familiarity with the 510(k) process, you 24 don't hold yourself out as an expert in the</p>

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<p>1 510(k) clearance process, correct?</p> <p>2 A Correct.</p> <p>3 Q You're not an expert on FDA</p> <p>4 regulations, correct?</p> <p>5 A I'm not a regulatory expert, correct.</p> <p>6 Q Have you ever reviewed a company's</p> <p>7 510(k) submission to the FDA before you became</p> <p>8 an expert in mesh litigation?</p> <p>9 A I have worked as an industry consultant</p> <p>10 on and off for the last 25 years. There have</p> <p>11 been products where things were coming to market</p> <p>12 and as part of an advisory group, I have looked</p> <p>13 at the 510(k) applications. I don't know</p> <p>14 specifically which products those would have</p> <p>15 been, but I have seen the applications.</p> <p>16 Q Have you ever provided feedback to the</p> <p>17 company submitting the 510(k) applications on</p> <p>18 the content of the application and what should</p> <p>19 or should not be in it?</p> <p>20 A Well, I know that when I reviewed some</p> <p>21 of these before they were submitted -- and I</p> <p>22 wasn't just by myself, it was usually with a</p> <p>23 group of people, and we would look at these.</p> <p>24 There were times when we would make suggestions</p>	<p>1 Q Have you ever reviewed Federal statutes</p> <p>2 or regulations on whether a product is</p> <p>3 misbranded or adulterated?</p> <p>4 A I do not recall.</p> <p>5 Q As you sit here today, is it fair to</p> <p>6 say that you don't have an understanding of what</p> <p>7 Federal statutes or regulations address</p> <p>8 misbranding or adulteration of products?</p> <p>9 A Not today, no.</p> <p>10 Q Am I correct that you will not be</p> <p>11 offering opinions at trial regarding whether</p> <p>12 Ethicon complied with FDA requirements or</p> <p>13 regulations in its sale of Prolift or in its</p> <p>14 labeling for Prolift?</p> <p>15 A Just what I put in my expert report on</p> <p>16 2A.</p> <p>17 Q You indicate here that Ethicon brought</p> <p>18 Prolift to market without FDA 510(k) clearance,</p> <p>19 correct?</p> <p>20 A That is correct.</p> <p>21 Q Am I correct that --</p> <p>22 MR. MATTHEWS: I can state in my place</p> <p>23 that he will not be offering an opinion on that</p> <p>24 at trial. You can ask him about it all you</p>
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<p>1 if we thought things needed to be added. I</p> <p>2 don't know that I ever said something should</p> <p>3 have ever been omitted.</p> <p>4 Q You made suggestions on additions to</p> <p>5 make to the 510(k) application itself?</p> <p>6 A Correct.</p> <p>7 Q And what product or submission was</p> <p>8 that?</p> <p>9 A I have been part of these groups on so</p> <p>10 many products, I don't specifically remember</p> <p>11 because it wasn't something that I would have</p> <p>12 ever thought I would have needed to remember. I</p> <p>13 just remember looking at the binders. I'm</p> <p>14 trying to think.</p> <p>15 Q Let me ask you, when was the last time</p> <p>16 you recall providing such feedback?</p> <p>17 A It would have been before 2003.</p> <p>18 Q So it would have been at least 13 years</p> <p>19 ago that you would have provided such feedback,</p> <p>20 correct?</p> <p>21 A Correct.</p> <p>22 Q Have you ever reviewed the FDA guidance</p> <p>23 document on when to submit a 510(k)?</p> <p>24 A I don't recall.</p>	<p>1 want.</p> <p>2 MS. KABBASH: On 2A?</p> <p>3 MR. MATTHEWS: 2A.</p> <p>4 MS. KABBASH: Okay. I will rely on</p> <p>5 that representation.</p> <p>6 BY MS. KABBASH:</p> <p>7 Q Dr. Garely, would you agree with me</p> <p>8 that there is no transvaginal mesh kit to treat</p> <p>9 prolapse that has been the subject of more</p> <p>10 studies than Prolift? Would you agree with</p> <p>11 that?</p> <p>12 A I have not done an independent research</p> <p>13 into the other mesh kits for me to be able to</p> <p>14 say that Prolift has had the most amount of</p> <p>15 research. I cannot say that.</p> <p>16 Q So as we sit here today, you don't know</p> <p>17 whether that's true or not?</p> <p>18 A Not to my -- not to my memory.</p> <p>19 Q Do you know if Prolift has more RCTs in</p> <p>20 particular studying it than other manufacturers'</p> <p>21 mesh kits?</p> <p>22 A I have not delved into the research of</p> <p>23 the other mesh kits. I cannot say.</p> <p>24 Q So you have not studied the quality and</p>

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<p>1 volume of the medical literature about Prolift</p> <p>2 vis-à-vis the other mesh kits put out by the</p> <p>3 other manufacturers, correct?</p> <p>4 A I'm sorry. I don't understand the</p> <p>5 question.</p> <p>6 Q That was a bad question. You have not</p> <p>7 done an analysis to assess the medical</p> <p>8 literature addressing Prolift compared to the</p> <p>9 medical literature studying other manufacturers'</p> <p>10 mesh kits, correct?</p> <p>11 A I have studied other manufacturers'</p> <p>12 mesh kits. I just don't know if the absolute</p> <p>13 body of knowledge is greater on those kits</p> <p>14 versus this kit.</p> <p>15 Q So you have not made that comparative</p> <p>16 analysis, correct?</p> <p>17 A Not in a formal sense, no.</p> <p>18 Q Do you agree that Prolift has</p> <p>19 demonstrated superiority to native tissue</p> <p>20 repairs in RCTs in demonstrating anatomic</p> <p>21 success?</p> <p>22 A In some studies on anterior wall</p> <p>23 repairs, there has been a greater success rate,</p> <p>24 but not on apical or posterior, and that's just</p>	<p>1 article again, which is Exhibit --</p> <p>2 A 15.</p> <p>3 Q 15, okay. Let's take a look at page</p> <p>4 1573. And you are second listed author on this</p> <p>5 article, correct?</p> <p>6 A That's correct.</p> <p>7 Q If you look at page 1573, towards the</p> <p>8 bottom of the first column.</p> <p>9 A Bottom?</p> <p>10 Q Here, it's a short column.</p> <p>11 A Oh, okay.</p> <p>12 Q Do you see there?</p> <p>13 A So the part that's right here?</p> <p>14 Q Right, exactly.</p> <p>15 In the middle of that paragraph, you're</p> <p>16 addressing different types of mesh kits,</p> <p>17 correct, you mention the Apogee, Avaulta and you</p> <p>18 mention Prolift, correct?</p> <p>19 A Give me a minute. I just want to get</p> <p>20 oriented. I haven't seen this paper in a while.</p> <p>21 Okay.</p> <p>22 Q Back to where we were in the middle of</p> <p>23 that left column, you've referenced various</p> <p>24 transvaginal mesh kits, including the Prolift,</p>
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<p>1 looking in a vacuum, a structural repair, it</p> <p>2 doesn't have to do with anything functional or</p> <p>3 in terms of complications.</p> <p>4 Q Right. And I'm not asking about</p> <p>5 complications or functional repairs. I'm asking</p> <p>6 if -- I think you've indicated that there are</p> <p>7 RCTs that demonstrate at least in the anterior</p> <p>8 compartment that Prolift has demonstrated</p> <p>9 superiority to native tissue repairs in</p> <p>10 demonstrating anatomic success in the anterior</p> <p>11 compartment, correct?</p> <p>12 A That's correct.</p> <p>13 Q And which studies are you referring to?</p> <p>14 Is that the Altman and Withagen?</p> <p>15 A Withagen.</p> <p>16 Q Yeah, Wit-hog-an (phonetic).</p> <p>17 A You don't speak Dutch?</p> <p>18 Q I don't.</p> <p>19 A Yes, I mean, I would have to see the</p> <p>20 actual studies because I don't recall them all</p> <p>21 off the top of my head. Altman and Withagen</p> <p>22 have written multiple papers, so I'd have to see</p> <p>23 the papers that you're referring to.</p> <p>24 Q Let's take a look back to your MRI</p>	<p>1 correct?</p> <p>2 A Correct.</p> <p>3 Q And then you go on to say starting at</p> <p>4 the bottom of that column, "These new mesh</p> <p>5 techniques offer the advantage of rebuilding the</p> <p>6 uterosacral cardinal ligament complex and</p> <p>7 providing rectovaginal fascial support and</p> <p>8 decreasing the dependence of the repair on a</p> <p>9 fixation point of either suture or mesh."</p> <p>10 And then you go on to say, "Short-term</p> <p>11 followup studies have shown lower failure rates</p> <p>12 with mesh kits compared to traditional repairs."</p> <p>13 That's what you indicate there, correct?</p> <p>14 A Correct.</p> <p>15 Q And it goes on to say, "Reported</p> <p>16 success rates range from 87 percent to 95</p> <p>17 percent at three to four" -- "14 months of</p> <p>18 followup." So that's what you're reporting</p> <p>19 about the success rates of mesh kits at that</p> <p>20 time, correct?</p> <p>21 A In this reference, three to 14-month</p> <p>22 followup, correct.</p> <p>23 Q And that reference was the Feiner</p> <p>24 article from 2009, correct?</p>

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<p>1 A Correct.</p> <p>2 Q And you go on to say, "The most common</p> <p>3 complications reported include vaginal mesh</p> <p>4 erosions in 5 to 11 percent and dyspareunia in</p> <p>5 1.5 to 3 percent." And for that proposition,</p> <p>6 you again cite the Feiner article, correct?</p> <p>7 A Correct.</p> <p>8 Q So at this point in time, the -- again,</p> <p>9 this was in 2012 that this article was</p> <p>10 published, correct?</p> <p>11 A Yeah, and that was relying on a</p> <p>12 systematic review from 2009.</p> <p>13 Q Okay.</p> <p>14 A From the British journal of -- journal</p> <p>15 of medical whatever.</p> <p>16 Q And that was a systematic review of</p> <p>17 many studies, correct?</p> <p>18 A Correct.</p> <p>19 Q Going back to our Oxford levels of</p> <p>20 evidence, one reason why you found that</p> <p>21 systematic review to be reliable is because</p> <p>22 systematic reviews are considered to be among</p> <p>23 the higher levels of evidence, correct?</p> <p>24 A More or less, yeah.</p>	<p>1 metaanalysis for the 5 to 11 percent rate of</p> <p>2 exposure, would you agree with me that the bulk</p> <p>3 of the medical literature on transvaginal mesh</p> <p>4 kits reports an exposure rate that is consistent</p> <p>5 with that range, recognizing that there are</p> <p>6 outliers lower and higher, but the 5 to 11</p> <p>7 percent that you reported here is consistent</p> <p>8 with the bulk of the medical literature on mesh</p> <p>9 exposure from transvaginal mesh kits, correct?</p> <p>10 A Well, in general, the lower range is</p> <p>11 not more consistent. It's mostly with the upper</p> <p>12 range.</p> <p>13 Q 11 percent?</p> <p>14 A 11 percent or more.</p> <p>15 Q And you also reported here based on the</p> <p>16 Feiner article that there were dyspareunia found</p> <p>17 in 1.5 to 3 percent of patients, correct?</p> <p>18 A Right. We're just citing what was</p> <p>19 already published in another journal. It wasn't</p> <p>20 the purpose of our paper.</p> <p>21 Q But certainly in putting together this</p> <p>22 article, you would only cite to sources that you</p> <p>23 found were reliable and accurately portrayed</p> <p>24 information as best you could tell, correct?</p>
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<p>1 Q And in that systematic review of many</p> <p>2 trials, the erosion rates that you were citing</p> <p>3 in this article fell within a range of 5 to 11</p> <p>4 percent for transvaginal mesh kits, correct?</p> <p>5 A From that journal article, the way they</p> <p>6 referenced the erosion rates, that's correct.</p> <p>7 Q And, Doctor, have you seen the recent</p> <p>8 MAR 2016 Cochrane review on the treatment of</p> <p>9 prolapse?</p> <p>10 A I don't recall if I -- if I read it.</p> <p>11 Do you have a copy of it?</p> <p>12 Q I do. We can talk about it in a little</p> <p>13 bit, but as of right now, you're not sure if</p> <p>14 you've read that one?</p> <p>15 A MAR has written a bunch of papers.</p> <p>16 This is a Cochrane review?</p> <p>17 Q Right. This is a Cochrane review that</p> <p>18 just came out in 2016, like just a couple of</p> <p>19 months ago.</p> <p>20 A Oh, I don't know that I've seen it yet.</p> <p>21 Q Okay.</p> <p>22 A Okay.</p> <p>23 Q Doctor, would you agree with me that</p> <p>24 even though you're citing a particular</p>	<p>1 A As best we could tell.</p> <p>2 Q You certainly would not cite that</p> <p>3 information if you had reason to believe that</p> <p>4 the information in it was inaccurate, correct?</p> <p>5 A It seemed reasonable at the time.</p> <p>6 Q And next you go on to say, "Randomized</p> <p>7 controlled trials comparing vaginal mesh repair</p> <p>8 to conventional vaginal colporrhaphy repair</p> <p>9 demonstrates higher anatomic success after</p> <p>10 tension-free vaginal mesh insertion, though</p> <p>11 symptom decrease and improved quality of life</p> <p>12 were equal in both groups." Correct?</p> <p>13 A Those were the anterior vaginal wall</p> <p>14 findings, correct.</p> <p>15 Q And those were the findings --</p> <p>16 A Perhaps we could have been more</p> <p>17 specific in that description. I mean, when you</p> <p>18 write these papers, sometimes in retrospect when</p> <p>19 you go back you realize you should have been</p> <p>20 more clear. Perhaps we could have been clearer</p> <p>21 that it was applying to the anterior wall.</p> <p>22 Q And that's fine. In making this</p> <p>23 statement here in this article, you have cited</p> <p>24 two randomized controlled trials, correct?</p>

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<p>1 A Correct.</p> <p>2 Q The first one, which is footnote 13, is</p> <p>3 the Withagen study?</p> <p>4 A The first one was number 12.</p> <p>5 Q I apologize.</p> <p>6 A That was Altman.</p> <p>7 Q That was Altman. And the Altman RCT</p> <p>8 studied Prolift versus anterior colporrhaphy,</p> <p>9 correct?</p> <p>10 A Correct.</p> <p>11 Q And the reference 13 is to the Withagen</p> <p>12 study and that also studied Prolift versus</p> <p>13 conventional vaginal repair, correct?</p> <p>14 A Correct.</p> <p>15 Q Okay. Let's take a look at your report</p> <p>16 at page 10. Before we get to that, Doctor,</p> <p>17 whenever -- strike that.</p> <p>18 Did you ever express concern to Ethicon</p> <p>19 about the IFUs for either TVT or TVT-O? Well,</p> <p>20 first let me ask you, have you ever seen the</p> <p>21 IFUs for either TVT Retropubic or TVT Obturator,</p> <p>22 the Gynecare brand name?</p> <p>23 A Yes.</p> <p>24 Q Did you ever express any concerns to</p>	<p>1 appropriately capable of doing the procedures.</p> <p>2 And we knew this because when they were</p> <p>3 sending people to precept with us, the people</p> <p>4 would ask questions like, oh, how do you hold</p> <p>5 that cystoscope? And we knew that if they</p> <p>6 didn't know how to use a cystoscope, these were</p> <p>7 not the people that should be implanting the</p> <p>8 device.</p> <p>9 So we had specifically requested to</p> <p>10 them that they make a criteria for the use of</p> <p>11 the product be properly trained or having a</p> <p>12 proper background, because we didn't think that</p> <p>13 it was appropriate for us to train someone by</p> <p>14 letting them watch us do three procedures and</p> <p>15 then letting them go back home to their</p> <p>16 institution and throw a device into a human</p> <p>17 being.</p> <p>18 So there was a lot of discussion at the</p> <p>19 time amongst the preceptors that that was --</p> <p>20 that there was not an appropriate screening</p> <p>21 process for people who were coming across to do</p> <p>22 the slings.</p> <p>23 Q Okay. So am I understanding you</p> <p>24 correctly, Doctor, that the nature of your</p>
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<p>1 Ethicon at any time about the adequacy of those</p> <p>2 IFUs, for TVT Retropubic or TVT Obturator?</p> <p>3 A I don't know that I specifically made a</p> <p>4 comment to them about the IFUs. I think that</p> <p>5 when I stopped -- I wasn't really a big TVT-O</p> <p>6 user for Gynecare for Ethicon brand, so when</p> <p>7 I -- so I don't know that I would have gone out</p> <p>8 of my way to have expressed my opinion about</p> <p>9 their products since I really wasn't using it.</p> <p>10 And I don't have any problems with the IFU for</p> <p>11 the TVT.</p> <p>12 Q Okay. So as you sit here today, you</p> <p>13 don't recall ever expressing concerns to Ethicon</p> <p>14 with regard to the risk warnings in the TVT</p> <p>15 Obturator IFU, you don't have any specific</p> <p>16 recollection of voicing such concerns as you sit</p> <p>17 here now?</p> <p>18 A The only thing that I would add to</p> <p>19 that, not specific to the TVT-O, but I did</p> <p>20 express multiple concerns about the TVT when I</p> <p>21 was in the thick of it as a preceptor, and it</p> <p>22 wasn't just me. Many of us that were teaching</p> <p>23 were concerned with the IFU in that we didn't</p> <p>24 think that they were selecting people who were</p>	<p>1 concern or criticism at the time was not the IFU</p> <p>2 per se, but it was the training level of certain</p> <p>3 surgeons who were coming to train with you at</p> <p>4 the time?</p> <p>5 A Well, it transcends that because we</p> <p>6 knew the IFU didn't have anything specific in it</p> <p>7 about the background or training of the person</p> <p>8 who was doing the procedure.</p> <p>9 Q Do you recall, Doctor, that the TVT IFU</p> <p>10 even to its earliest iterations contained</p> <p>11 language in it saying that surgeons using this</p> <p>12 device must be appropriately trained in surgical</p> <p>13 procedures to treat SUI and in the use of this</p> <p>14 device? As you sit here today, do you have</p> <p>15 recollection of that language being in the TVT</p> <p>16 IFU for the past 16 years back to its launch?</p> <p>17 A I do not.</p> <p>18 Q If it did have such language in it,</p> <p>19 that would at least in part speak to the concern</p> <p>20 that you are discussing right now, correct?</p> <p>21 A It would.</p> <p>22 Q Let's look at page 10 of your report.</p> <p>23 And the first full paragraph starts, "The</p> <p>24 biomechanical incompatibility." Do you see</p>

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<p>1 that?</p> <p>2 A I do.</p> <p>3 Q It says, "The biomechanical</p> <p>4 incompatibility of the Gynemesh PS with the</p> <p>5 female pelvis which Ethicon failed to study or</p> <p>6 establish before selling the product was also</p> <p>7 demonstrated in a published study involving the</p> <p>8 vaginal implantation of three types of mesh in</p> <p>9 monkeys." Do you see that?</p> <p>10 A I do.</p> <p>11 Q And there you reference I think the</p> <p>12 Mark Lang study. As I think you indicate,</p> <p>13 Doctor, the Lang study, it's an animal study,</p> <p>14 correct?</p> <p>15 A Correct.</p> <p>16 Q It involved three monkeys, correct?</p> <p>17 A Correct. Three types of mesh in</p> <p>18 monkeys. I don't -- I would have to see the</p> <p>19 study, I don't remember how many monkeys.</p> <p>20 Q Do you find that a study involving</p> <p>21 implantation in a monkey is more instructive of</p> <p>22 the safety of a device than the RCTs that</p> <p>23 analyze the use of that device in real women?</p> <p>24 A Do I think that the animal study is</p>	<p>1 lot of the problems" forward.</p> <p>2 Q But you would agree, Doctor, that in</p> <p>3 terms of assessing how the mesh is going to</p> <p>4 perform in human women, the best source of</p> <p>5 information to look to is the studies that</p> <p>6 actually study the use of that mesh in women and</p> <p>7 not in monkeys, correct? That is a better</p> <p>8 source of information than a monkey study,</p> <p>9 correct?</p> <p>10 A Which is why we know now that the mesh</p> <p>11 was problematic because when it was implanted in</p> <p>12 women, it demonstrated so many problems.</p> <p>13 MS. KABBASH: Move to strike.</p> <p>14 Q My question is, Doctor, would you agree</p> <p>15 that in assessing whether a mesh is</p> <p>16 biocompatible in women, clinical studies</p> <p>17 assessing that mesh in women is more instructive</p> <p>18 and reliable than an animal study assessing that</p> <p>19 mesh in monkeys; would you agree with that</p> <p>20 statement, that general statement?</p> <p>21 A In general, it's better to do a trial</p> <p>22 on a human being.</p> <p>23 Q Let's look at opinion 5 on page 10.</p> <p>24 And there you indicate your opinion that the</p>
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<p>1 better than a randomized controlled trial in</p> <p>2 humans?</p> <p>3 Q In assessing the biomechanical</p> <p>4 compatibility of the mesh?</p> <p>5 A I don't -- I think that the animal</p> <p>6 studies can give you information about some</p> <p>7 parts -- some properties of the material that</p> <p>8 you're implanting into humans, but there are</p> <p>9 reasons why you want to do things in animals and</p> <p>10 there are reasons why you want to do things in</p> <p>11 humans. I think that the purpose of the</p> <p>12 implantation in the animals in this particular</p> <p>13 study were to just get a baseline understanding</p> <p>14 of how the mesh would do in a biologic, living</p> <p>15 condition.</p> <p>16 I think that ultimately the randomized</p> <p>17 controlled trial in a human is going to give you</p> <p>18 the best information in how it's going to</p> <p>19 perform in a human. A lot of the problems with</p> <p>20 this mesh had to do with the mesh load. It had</p> <p>21 to do with the volume, the surface area of the</p> <p>22 mesh, which is why this mesh performed</p> <p>23 differently than mesh that's placed for a TVT.</p> <p>24 MS. KABBASH: Move to strike from "A</p>	<p>1 mesh in the Prolift kits is too stiff for its</p> <p>2 intended application?</p> <p>3 A I see it.</p> <p>4 Q Okay. On the next page, you say, "In</p> <p>5 light of the published literature establishing</p> <p>6 that mesh can be or become rigid or restrictive,</p> <p>7 Ethicon should not have used this material in</p> <p>8 the vagina, which has much greater sensitivity</p> <p>9 and requires far greater flexibility than the</p> <p>10 abdomen."</p> <p>11 And by the way, that reference to the</p> <p>12 abdomen, just above that, you're relying for</p> <p>13 that opinion on references in the hernia</p> <p>14 literature, correct?</p> <p>15 A Correct.</p> <p>16 Q Then you go on to say, "The fibrotic</p> <p>17 scar that encapsulates the mesh used in the</p> <p>18 Prolift implant due to its defective design</p> <p>19 features causes greater rigidity, less</p> <p>20 flexibility and pain."</p> <p>21 And you hold the same opinion not only</p> <p>22 with regard to the Prolift, but with regard to</p> <p>23 the Prolift+M also, correct?</p> <p>24 A That's correct, based on the documents</p>

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<p>1 that were provided to me from Johnson & Johnson, 2 this is what they were utilizing as the basis of 3 their usage of the mesh in the vagina. So it 4 wasn't that I just decided to go to abdominal 5 mesh. I relied on the same materials that the 6 people who were formulating Prolift and 7 Prolift+M were using.</p> <p>8 Q So you -- in forming this opinion, you 9 were relying on company documents that have been 10 provided to you, correct?</p> <p>11 A That and the literature, my own 12 independent literature search.</p> <p>13 Q And your review of the hernia 14 literature?</p> <p>15 A Correct.</p> <p>16 Q Doctor, would you agree that the 17 Prolene -- branded Prolene material that is in 18 the Gynemesh PS, is the same Prolene that is in 19 TVT slings, but in a different knit?</p> <p>20 A Same Prolene, different knit?</p> <p>21 Q Right.</p> <p>22 A Yes.</p> <p>23 Q You agree with that?</p> <p>24 A I don't have any reason to disagree</p>	<p>1 notion that there is fibrotic bridging 2 demonstrated over the TVT implants when they are 3 used; do you agree with that?</p> <p>4 MR. MATTHEWS: And you're talking about 5 TVT-O, all the TVT --</p> <p>6 MS. KABBASH: The Gynecare TVT family 7 of products because they have the same implant.</p> <p>8 A No, I think there is fibrotic bridging 9 that occurs. Especially in -- well, there's 10 fibrotic bridging that occurs in all the meshes, 11 but the reason that the TVT Retropubic is 12 different is because it's the space that it's 13 placed in and the way that the load of the mesh, 14 the TVT Obturator behaves in a similar way to 15 transvaginal mesh for prolapse because of the 16 way it's positioned.</p> <p>17 So it has to do -- there are multiple 18 factors that influence the way the a mesh 19 behaves in the vaginal area. It -- there's -- 20 there's fibrotic bridging that occurs in all of 21 these meshes. For me to say that the fibrotic 22 bridging somehow is safe in one product or less 23 in product and then it's applicable to another 24 product, I cannot do that, I can't do that.</p>
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<p>1 with that. That's my understanding.</p> <p>2 Q Okay. Would you agree with me that the 3 body of evidence on TVT slings do not 4 demonstrate fibrotic bridging over the TVT 5 slings, and I mean that the whole TVT family, 6 whether obturator or retropubic.</p> <p>7 A I'm sorry, repeat the question.</p> <p>8 Q Sure. I assume that since TVT came out 9 in 1998, you have reviewed the body of 10 literature on the TVT, correct?</p> <p>11 A Correct.</p> <p>12 Q And that's been an important part of 13 your practice, to stay current on the medical 14 literature of the products that you use, 15 correct?</p> <p>16 A Correct.</p> <p>17 Q And there has now amassed almost 20 18 years of medical literature, in fact, 20 years 19 of medical literature on the use of TVT since 20 Uhmston first published on it in the 1990s, 21 correct?</p> <p>22 A Correct.</p> <p>23 Q And would you agree with me that that 24 body of medical literature does not support the</p>	<p>1 BY MS. KABBASH:</p> <p>2 Q In the TVT context, is it your opinion 3 that the fibrotic bridging that occurs has 4 negative clinical impact on the patient?</p> <p>5 A In a situation of TVT Retropubic, I 6 don't believe that it is a negative, no.</p> <p>7 Q When you say "fibrotic bridging," what 8 do you mean exactly?</p> <p>9 A Fibroblasts that reach across to each 10 other from one strand of the mesh to another 11 strand of the mesh causing scar plate formation 12 and hardening in a firmness. That's -- given 13 the surface area of the mesh that's in contact 14 under the urethra is 2 centimeters. We're not 15 talking about 2 centimeters by 2 centimeters 16 which is a square area of 4 centimeters.</p> <p>17 We're talking about the width and 18 length of the mesh that goes into the vagina for 19 transvaginal mesh procedures where the surface 20 areas can approximate -- even if you have 5 21 centimeters by 4 centimeters, that's 20 square 22 centimeters of mesh.</p> <p>23 It's a big mesh load. The tissue 24 behaves differently. You can't -- it's</p>

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<p>1 comparing apples to oranges. That's what I'm</p> <p>2 saying.</p> <p>3 Q Do you agree that the pore size of</p> <p>4 Gynemesh PS is larger than that of the TVT mesh?</p> <p>5 A Again, I haven't reviewed the pore</p> <p>6 size. You told me it was 1.3?</p> <p>7 Q Yes.</p> <p>8 A And we're comparing it to --</p> <p>9 Q If I represented to you that Gynemesh</p> <p>10 PS and Prolift mesh had a pore size of 2.4</p> <p>11 millimeters, does that sound right to you?</p> <p>12 MR. MATTHEWS: Object to the form of</p> <p>13 the question in that it misstates the evidence.</p> <p>14 You can answer it.</p> <p>15 BY MS. KABBASH:</p> <p>16 Q Have you seen -- well, actually -- hang</p> <p>17 on. Let me restate the question.</p> <p>18 Have you seen company documents that</p> <p>19 indicate that the pore size for Prolift and</p> <p>20 Gynemesh PS is 2.4 millimeters?</p> <p>21 A I don't recall that it was 2.4</p> <p>22 centimeters. If you could show it to me, then I</p> <p>23 would remember it.</p> <p>24 Q Sitting here right now, you cannot</p>	<p>1 A Yes.</p> <p>2 Q Which study?</p> <p>3 A Well, I cite different papers in my</p> <p>4 footnotes in different parts of this paper.</p> <p>5 Q Where are you?</p> <p>6 A I'm on page 12. And talking about</p> <p>7 excessive scarification and shrinkage, when</p> <p>8 there's shrinkage, there's a decrease in the</p> <p>9 pore size. That's reference 22.</p> <p>10 Q Reference 22 is to Ethicon cadaver</p> <p>11 labs, correct?</p> <p>12 A That reference for that point.</p> <p>13 Q But my question is, can you point me to</p> <p>14 a study piece -- a published -- peer-reviewed</p> <p>15 published medical literature?</p> <p>16 Let me ask a more precise question.</p> <p>17 Can you point me to any peer-reviewed published</p> <p>18 medical literature that has concluded that the</p> <p>19 pores in Ethicon's Prolift mesh collapse or</p> <p>20 deform to be less than 1 millimeter?</p> <p>21 A Well, the -- there's the same mesh that</p> <p>22 was used on abdominal hernia repairs</p> <p>23 demonstrated shrinkage. I don't -- I'd have to</p> <p>24 see the papers right in front of me to recall</p>
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<p>1 recall that?</p> <p>2 A Well, there were so many different</p> <p>3 iterations of the pore size based on whether it</p> <p>4 was at rest or whether it was at stretch or</p> <p>5 tension or whether -- the axis of the stretch</p> <p>6 occurred. So know that greater than 1</p> <p>7 millimeter was good and 2.4, that was better</p> <p>8 than 1, but there was a distortion of the pores</p> <p>9 that occurred, once the tissue was implanted --</p> <p>10 once the material was implanted into the tissue.</p> <p>11 Q On what are you basing your opinion</p> <p>12 that there was a distortion of the pores that</p> <p>13 occurred? What body of information is that</p> <p>14 opinion based on?</p> <p>15 A It's in my -- somewhere in my report,</p> <p>16 but it was based on internal documents from</p> <p>17 research that I had looked at that was done by</p> <p>18 Johnson & Johnson.</p> <p>19 Q Okay. Are you pointing to any --</p> <p>20 besides company documents, which you've just</p> <p>21 discussed, is there any medical literature that</p> <p>22 you can specifically point me to that concludes</p> <p>23 that the pores in Prolift mesh deform or</p> <p>24 distort?</p>	<p>1 whether or not they said that the pore size</p> <p>2 actually shrunk. I need a minute to just take a</p> <p>3 look.</p> <p>4 Q Why don't we go off the clock for a</p> <p>5 second, and you can take a look to find it.</p> <p>6 A Okay.</p> <p>7 (Whereupon, a brief recess is</p> <p>8 taken.)</p> <p>9 THE WITNESS: Okay.</p> <p>10 BY MS. KABBASH:</p> <p>11 Q Okay?</p> <p>12 A What I was relying on was the internal</p> <p>13 documents from Ethicon which are cited as</p> <p>14 number 6 and number 7. Those would be --</p> <p>15 Q I apologize. What page are you on?</p> <p>16 A It would be page 9. The top paragraph</p> <p>17 number 3 with reference number 6 and reference</p> <p>18 number 7. Those were internal documents done by</p> <p>19 Ethicon.</p> <p>20 So off the top of my head, no, I cannot</p> <p>21 cite a published paper, but Ethicon knew from</p> <p>22 their own internal research that the pores did</p> <p>23 shrink down to less than 1 millimeter.</p> <p>24 Q Okay. So just to make the record</p>

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<p>1 clear, as we sit here right now, you cannot</p> <p>2 point me to a piece of published medical</p> <p>3 literature which concludes that the pore size of</p> <p>4 Prolift mesh deforms to less than 1 millimeter,</p> <p>5 correct, as we sit here right now?</p> <p>6 A Well, there's -- I mean, I don't have</p> <p>7 my PubMed in front of me, but if I'm -- and I</p> <p>8 don't know that I can recall specifically that</p> <p>9 Klausterhoffen made a note about pore size. But</p> <p>10 I think that one of his papers did discuss</p> <p>11 shrinkage of pore size, but I can't be a hundred</p> <p>12 percent certain without looking at the paper.</p> <p>13 Q And you have not cited that paper in</p> <p>14 your report, correct?</p> <p>15 A I don't think I did.</p> <p>16 Q Okay. You also have -- let's go to</p> <p>17 page 11 of your report, which I think we're</p> <p>18 already here. Opinion number 6, you say, "As</p> <p>19 the Prolift mesh scars in, the resulting</p> <p>20 shrinkage or contracture of the tissues</p> <p>21 surrounding the mesh can entrap nerves, deform</p> <p>22 the vagina and pelvic anatomy," et cetera. And</p> <p>23 then you go on to say below that, you discuss</p> <p>24 nerve entrapment with chronic pain. Do you see</p>	<p>1 entrapment of tiny nerves, to the extent that it</p> <p>2 happens, is something that has to be viewed</p> <p>3 under a microscope? In other words, you cannot</p> <p>4 clinically discern the entrapment of tiny nerves</p> <p>5 in mesh, right? You have to view that under a</p> <p>6 microscope to see that, correct?</p> <p>7 A Well, if a patient has pain at the site</p> <p>8 of where the mesh is, and if you take the mesh</p> <p>9 out and it relieves the pain, we're all I'm sure</p> <p>10 in agreement that nerves cause pain, so there</p> <p>11 would be nothing else other than nerve issues</p> <p>12 surrounding the mesh that would be causing the</p> <p>13 pain.</p> <p>14 So do I need a microscope to confirm</p> <p>15 nerve presence in a mesh? I do not. But if you</p> <p>16 wanted to say, hey, are there nerves in this</p> <p>17 mesh, then you would need to do appropriate</p> <p>18 nerve stains and use a microscope, but from a</p> <p>19 clinical perspective, that's not something that</p> <p>20 you would care about the patient, if patients</p> <p>21 got better by removing the mesh.</p> <p>22 Q From a clinical perspective, if you --</p> <p>23 if a patient was in pain, and you removed the</p> <p>24 mesh, you would -- and the patient got better</p>
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<p>1 that?</p> <p>2 A I do.</p> <p>3 Q You say sometimes after one year there</p> <p>4 are no complaints and then complaints happen --</p> <p>5 oh, I'm sorry, you're quoting something here, an</p> <p>6 Ethicon surgeon panel meeting, and it goes on to</p> <p>7 say, "Often the result of tiny nerves in the</p> <p>8 granuloma and that's just a matter of" -- strike</p> <p>9 that.</p> <p>10 In this opinion, you were making -- you</p> <p>11 were opining that patients may suffer</p> <p>12 complications from tiny nerves that get</p> <p>13 entrapped in the mesh, correct?</p> <p>14 A I was opining that I agreed with</p> <p>15 Ethicon's surgeon panel's assessment. I was</p> <p>16 agreeing with them.</p> <p>17 Q And that opinion is that tiny nerves</p> <p>18 can get entrapped in the mesh due to</p> <p>19 contraction, correct?</p> <p>20 A Yes.</p> <p>21 Q Okay. And you also hold this same</p> <p>22 opinion with respect to Prolift+M, correct?</p> <p>23 A I do.</p> <p>24 Q Okay. Would you agree that the</p>	<p>1 and the pain got better, you would deduce or</p> <p>2 make an assumption that there were nerves in the</p> <p>3 mesh, correct?</p> <p>4 A That's fair.</p> <p>5 Q To actually investigate the explants</p> <p>6 and see if there is evidence of nerves in the</p> <p>7 mesh, you would have to take that mesh, put it</p> <p>8 on a slide, and put it under a microscope and</p> <p>9 look at it, correct?</p> <p>10 A Well, it's a matter -- it's a point of</p> <p>11 semantics, but yes, if you wanted to actually</p> <p>12 prove it, it's not something that's done in</p> <p>13 common practice.</p> <p>14 Q I think plaintiff's expert pathologist</p> <p>15 might disagree with that, but...</p> <p>16 Am I correct that you were not trained</p> <p>17 in interpreting what can be viewed on explant</p> <p>18 slides under a microscope? In other words, not</p> <p>19 only have you not put a mesh slide under a</p> <p>20 microscope and looked at it, even if you had,</p> <p>21 you are not trained in how to interpret what</p> <p>22 you're seeing on that slide; is that correct?</p> <p>23 A Just from what I know from basic</p> <p>24 histology and pathology in medical school. And</p>

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<p>1 I did do two months of pathology as a resident 2 as well. 3 Q And that was about 20 years ago? 4 A I did that probably -- I did that 5 rotation in my second year of residency, that 6 was 1990. 7 Q Is it fair to say that if you -- if we 8 had a mesh that was on a slide and it got put 9 under the microscope, you would need the 10 assistance of a pathologist to be able to 11 properly and reliably interpret what was on that 12 mesh slide, correct? Or some other professional 13 with a background other than yours? 14 A I could probably muddle through it on 15 the bigger structures, but I would have a 16 problem on the smaller things. 17 Q Tiny nerves in particular, correct? 18 A I'm not really good at looking at tiny 19 nerves under the microscope. 20 Q You don't typically use a microscope to 21 make treatment recommendations and decisions for 22 your patients, correct? 23 A I do not. 24 Q And you don't use a microscope in order</p>	<p>1 portion, causing it to move and/or to change 2 shape in untended and unpredictable ways." 3 A I don't see it. Where are you reading? 4 Q Oh, I apologize. Page 12. 5 A Where? 6 Q I'll point you to it, if you don't 7 mind. 8 A Thank you. 9 Q And I read up to "unpredictable ways"? 10 A Right here, okay. 11 Q And a couple of lines below that it 12 says, The arms pulling on and deforming the 13 central mesh from their anchoring points in the 14 pelvic side wall muscles also causes pain during 15 daily activities, which necessarily exert forces 16 on the pelvic muscles and tissues." 17 And again, you hold this opinion both 18 as to the Prolift kit and the Prolift+M kit, 19 correct? 20 A Correct. 21 Q What body of information or source is 22 the basis for this opinion that the mesh arms 23 pull asymmetrically on -- what information or 24 source is the basis for this opinion in your</p>
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<p>1 to assess how to treat complications if you have 2 patients with complications, correct? 3 A I do not. 4 Q Do you know which stains need to be 5 used so that nerves can be seen on a mesh slide 6 under a microscope? 7 A I know for a fact that I used to know 8 the answer to this, but as I sit here today, I 9 do not recall. 10 Q Okay. Do you know what level of 11 magnification needs to be used so that nerves 12 can be viewed in a mesh explant? 13 A Now I feel bad that I didn't pay more 14 attention in pathology. I do not recall. 15 Q Okay. If we move to page 12 -- I'm 16 coming to a good stopping point soon, I'm just 17 trying to get there. I'm not trying to starve 18 you or anything, believe me. 19 As we come to page 12 of your report, 20 you have opinion number 7, and in the second 21 paragraph of opinion 7 or paragraph 7, you say, 22 "As the parts of the mesh arms of Prolift kits 23 incorporate into tissue via a scarring process, 24 they pull asymmetrically on the center mesh</p>	<p>1 report that the mesh arms pull asymmetrically on 2 the center mesh portion and deform the mesh? 3 A A lot of this was -- is my personal 4 experience working with the Prolift and the 5 Prolift+M. 6 Q What do you mean when you say working 7 with it because you've never implanted it, 8 correct? 9 A No, I'm talking about explanting it. 10 Q Okay. 11 A But the same -- the same can apply to 12 the implant because if you apply the skills that 13 I know from implanting the IVS Tunneller and the 14 TOT sling, they're the same entry points as the 15 Prolift and the Prolift+M. So in essence, I 16 have done exactly the same approaches and 17 techniques as it required for your implantation 18 of the Prolift and Prolift+M, but this is 19 specific to the experience I have with removing 20 this material as an explanting surgeon. 21 And everything that I've said in this 22 statement is things that are found not just by 23 me, but among all pelvic surgeons who are 24 explanting this mesh. This is -- these are</p>

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<p>1 what -- what -- when people talk about standard 2 of care, this is what we would accept to be as 3 standard body of knowledge among the specialty. 4 Everybody that removes this material 5 and works with it in any way, whether it's an 6 implant or an explant, every single person 7 understands that this mesh -- it's because of 8 the arms that the mesh starts to behave in 9 asymmetrical fashions and starts to cause 10 problems with sexual penetration, attempts at 11 defecation, urination, and these are 12 specifically related to the contracture of the 13 mesh specifically related to the arms. 14 Q Doctor, you make reference to what 15 every doctor knows; am I correct that you have 16 not done any kind of study or assessment of what 17 anyone other than you knows about the impact of 18 the mesh arms? You have not done an analysis of 19 that, correct? 20 A Perhaps I misspoke by saying "every." 21 I -- the better statement would have been the 22 majority. And I can speak for the majority 23 because these are things that we talk about at 24 our conferences all the time. I would -- it</p>	<p>1 Q I'll go with observe and that would 2 mean what you see or what you observe in any 3 other way. 4 A So the first thing that you notice is 5 when you put a speculum into the vagina to 6 assess the anterior vaginal wall or the 7 posterior vaginal wall or the apex is symmetry. 8 And in a patient who has had these mesh problems 9 from transvaginal mesh with arms, the first 10 thing you notice is that there's asymmetry of 11 the walls, meaning one side may be higher than 12 the other, and that tells you right away that 13 one side is either contracted or not contracted. 14 One side is lower. 15 The distance from the introitus to the 16 apex is shortened, it's not what you would 17 expect it to be in a normal anatomic vagina. 18 And that applies to the anterior wall and the 19 posterior wall. So just on observation and 20 palpation, you can assess what's happened with 21 this mesh before you even get into cutting or 22 removing it. 23 Then you can feel as the arms go 24 through these attachment points, whether it's</p>
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<p>1 would be virtually impossible for anyone to say 2 that less than 50 percent of pelvic surgeons do 3 not find these problems in transvaginal mesh 4 with arms. 5 Q You indicated before your experience. 6 Am I correct that the opinion that you 7 articulate here about the asymmetrically pulling 8 on the center portion of the mesh is based on 9 what you've seen in your practice? 10 A It's what I've seen on explanted meshes 11 on a regular basis. 12 Q And you've testified before that -- I 13 think it was 20 to 25 meshes that you have 14 explanted were Prolift or Prolift+M, correct? 15 A I think I said between 10 and 20 for 16 sure. More than 20, I couldn't say. 17 Q Okay. Thank you for correcting me. 18 And in those 10 to 20 Prolift or 19 Prolift+M explants, what did you see or observe 20 that leads you to conclude that the mesh arms 21 pull asymmetrically on the center mesh portion? 22 A You asked me two parts to that 23 question. What did I see or observe? Is that 24 what you said? I'm sorry.</p>	<p>1 the obturator or the -- where the anterior goes 2 through or the further ones in, which are near 3 the sacrospinous ligament, you can feel 4 contracture of the mesh arms and pulling. 5 When you're examining a patient while 6 they're awake, if you touch these points, these 7 are the points where the patient will experience 8 significant pain. Now, you can touch anywhere 9 else in the vagina, if there's no tension on it, 10 they may not experience pain. 11 But if you're asking me based on what 12 observation or assessment, that's my observation 13 and assessment. It doesn't look right. It's 14 not right. And then you know that when you go 15 in and you make a cut in the vagina and you 16 skeletonize and isolate the mesh, and you nip 17 and chip away at it, one muscle fiber, one 18 strand at a time until you skeletonize the mesh 19 out without injuring the bladder or the rectum. 20 And you finally cut it free from the 21 arms and the mesh pops out, when you remove it 22 and put it on a table and look at it, you know 23 that it's not symmetric, and you know that there 24 was contracture of the mesh, and you know the</p>

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<p style="text-align: right;">Page 194</p> <p>1 patient was in pain and suffering because of the</p> <p>2 way that this stuff healed.</p> <p>3 Q What is it about putting it on a table</p> <p>4 and looking at it that tells you that the mesh</p> <p>5 was asymmetric and pulling?</p> <p>6 A Because the mesh went in as one flat</p> <p>7 piece of material, and when you pull it out, it</p> <p>8 doesn't look like that. It's completely</p> <p>9 distorted.</p> <p>10 Q Distorted in what way?</p> <p>11 A The mesh arms are tubularized, they</p> <p>12 turn into small strings. There are a huge</p> <p>13 amount of tissue that's stuck to the underside</p> <p>14 of this. It doesn't -- it's -- it looks like a</p> <p>15 crumpled up piece of paper. It doesn't look</p> <p>16 like a flat sheet.</p> <p>17 Q In the explants that you've done for</p> <p>18 Prolift or Prolift+M, have you removed the mesh</p> <p>19 arms?</p> <p>20 A I have not gone beyond the obturator or</p> <p>21 the sacrospinous to remove the arms, but you can</p> <p>22 pull on the arms and you can cut with a scissor</p> <p>23 where you push tight against the muscle so that</p> <p>24 portions of the arms do come out.</p>	<p style="text-align: right;">Page 196</p> <p>1 a better bite next to the muscle.</p> <p>2 Q So your opinion about the roping and</p> <p>3 curling of the arms is based on what you've</p> <p>4 observed in the 10 to 20 Prolift explants that</p> <p>5 you've done, correct?</p> <p>6 A Well, in addition -- for sure, based on</p> <p>7 my assessments, but also you can look at number</p> <p>8 22 in my reference sheet, that in 2006, Ethicon</p> <p>9 conducted cadaver labs in which an Ethicon</p> <p>10 consultant demonstrated that the Prolift mesh</p> <p>11 arms deform upon implantation. They crumple.</p> <p>12 These labs also produced photographic</p> <p>13 evidence of arm deformation with Prolift arms</p> <p>14 that were later included in several of Ethicon's</p> <p>15 internal documents, explaining this phenomena as</p> <p>16 set forth below.</p> <p>17 And then I have an explanted picture</p> <p>18 and a photograph, and I have followed by</p> <p>19 additional photographs of where the arms</p> <p>20 tubularized and deform. And I'm basing my</p> <p>21 opinion based on my personal experience with</p> <p>22 explanting this device, in addition to</p> <p>23 supporting documents from Ethicon. So I agree</p> <p>24 with Ethicon.</p>
<p style="text-align: right;">Page 195</p> <p>1 I'm not saying that you're getting the</p> <p>2 bulk of the arm, but you're getting the -- the</p> <p>3 only way that you -- you can only pull the mesh</p> <p>4 through the obturator to the body of the mesh.</p> <p>5 You're only pulling the arms. You're not</p> <p>6 pulling the body of the material through the --</p> <p>7 through the tunnels.</p> <p>8 Q So when you're assessing whether the</p> <p>9 arms are roped or curled as you're mentioning in</p> <p>10 your report, that's based also on those 10 to 20</p> <p>11 explants?</p> <p>12 A Correct.</p> <p>13 Q And when you do that, that's after</p> <p>14 you've pulled on the arms so that you can remove</p> <p>15 it and observe it?</p> <p>16 A You're not pulling on the arms. You're</p> <p>17 skeletonizing the material to the side wall.</p> <p>18 The only pulling you're doing is just gentle</p> <p>19 traction so that you can put your scissor up</p> <p>20 against the obturator and cut it.</p> <p>21 If you leave it flaccid, there's a</p> <p>22 chance you'll possibly draw down some of the</p> <p>23 bladder or the rectum from below. So you put it</p> <p>24 on a little bit of a tension so that you can get</p>	<p style="text-align: right;">Page 197</p> <p>1 Q Am I correct, Doctor, that in this</p> <p>2 opinion, regarding the asymmetrical pulling on</p> <p>3 the arms and the roping and curling opinion,</p> <p>4 that in your report as you articulate these</p> <p>5 opinions, you have not relied on peer-reviewed</p> <p>6 medical literature to support these opinions?</p> <p>7 We've just discussed the cadaver lab</p> <p>8 that you just mentioned. We've discussed your</p> <p>9 experience with the 10 to 20 explants. Am I</p> <p>10 correct that in support of your roping and</p> <p>11 curling opinion and your asymmetrical pulling</p> <p>12 opinion, you are not relying in this report on</p> <p>13 peer-reviewed medical literature, correct?</p> <p>14 A I don't -- I don't know what else to</p> <p>15 call it when the -- when the arms rope and curl,</p> <p>16 other than roping and curling.</p> <p>17 MS. KABBASH: Move to strike.</p> <p>18 BY MS. KABBASH:</p> <p>19 Q You have not cited in your report on</p> <p>20 these two points any peer-reviewed medical</p> <p>21 literature that supports your opinions on</p> <p>22 roping, curling and asymmetrical pulling,</p> <p>23 correct?</p> <p>24 A I don't know that it's not included in</p>

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<p>1 any of the references that I've put forth into</p> <p>2 my expert report, but off the top of my head, I</p> <p>3 can't recall a specific paper where they noted</p> <p>4 roping and curling.</p> <p>5 Q Okay. Why don't we break for lunch.</p> <p>6 (Whereupon, a luncheon recess is</p> <p>7 taken.)</p> <p>8 MR. MATTHEWS: He'll read and sign.</p> <p>9 BY MS. KABBASH:</p> <p>10 Q Dr. Garely, we took a break for lunch.</p> <p>11 Are you ready to proceed?</p> <p>12 A Yes, ma'am.</p> <p>13 Q Dr. Garely, will you be offering an</p> <p>14 opinion at trial to a reasonable degree of</p> <p>15 medical certainty that polypropylene mesh</p> <p>16 degrades after implantation in the body?</p> <p>17 A Only what I've referenced in my expert</p> <p>18 report.</p> <p>19 Q You've referenced in your expert report</p> <p>20 -- you have a paragraph on page 23 that there's</p> <p>21 a statement in the IFU, "The material in</p> <p>22 Gynemesh is not absorbed nor is it subject to</p> <p>23 degradation or weakening by the action of tissue</p> <p>24 enzymes is contradicted by Ethicon internal</p>	<p>1 the IFU about degradation, correct?</p> <p>2 A That's my basis of opinion.</p> <p>3 Q Okay. There -- you have not cited in</p> <p>4 footnote 39 any medical literature,</p> <p>5 peer-reviewed medical literature to support your</p> <p>6 opinion, correct?</p> <p>7 A Correct.</p> <p>8 Q I have to ask the question again, sir.</p> <p>9 Am I correct that at trial you will not be</p> <p>10 opining to a reasonable degree of medical</p> <p>11 certainty that polypropylene mesh degrades</p> <p>12 within the body? Let me strike that.</p> <p>13 Is it your opinion to a reasonable</p> <p>14 degree of medical certainty that polypropylene</p> <p>15 mesh degrades within the body? Do you believe</p> <p>16 that?</p> <p>17 A I believe it has possibly -- I don't</p> <p>18 think the degradation related to the mesh is the</p> <p>19 major part of why this mesh is problematic.</p> <p>20 Q Okay. I appreciate that, but that</p> <p>21 wasn't my question. My question is, do you have</p> <p>22 an opinion to a reasonable degree of medical</p> <p>23 certainty that polypropylene mesh degrades</p> <p>24 within the body? That is not one of your</p>
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<p>1 documents and reports which clearly show that</p> <p>2 the material was subject to degradation inside</p> <p>3 the body."</p> <p>4 That's what your statement in your</p> <p>5 report is, correct?</p> <p>6 A Correct.</p> <p>7 Q So is your opinion that the line in the</p> <p>8 IFU is contradicted by Ethicon's internal</p> <p>9 documents?</p> <p>10 A I'm not saying that it's contradicted.</p> <p>11 I'm just saying that it's not substantiated by</p> <p>12 the documents that I reviewed based on the</p> <p>13 internal -- the internal documents from the</p> <p>14 company.</p> <p>15 Q And what documents are those that you</p> <p>16 reviewed?</p> <p>17 A It's reference 39.</p> <p>18 Q And in reference 39, you reference a</p> <p>19 series of internal Ethicon minutes and</p> <p>20 PowerPoint documents and internal memos,</p> <p>21 correct?</p> <p>22 A Correct.</p> <p>23 Q And that is the basis for your opinion</p> <p>24 that you -- we just discussed about the line in</p>	<p>1 opinions, is it, Doctor?</p> <p>2 A No, it's not.</p> <p>3 Q Certainly if you believe that, you</p> <p>4 wouldn't have implanted thousands of retropublic</p> <p>5 slings into women, correct?</p> <p>6 A Correct.</p> <p>7 Q Okay. So your sole opinion with</p> <p>8 respect to degradation is that the statement in</p> <p>9 the IFU that we just discussed is not supported</p> <p>10 by the internal company documents that you cite</p> <p>11 in footnote 39, correct?</p> <p>12 A I'm sorry, repeat that question.</p> <p>13 MS. KABBASH: Sure. Can I ask you,</p> <p>14 Dana, to repeat it?</p> <p>15 (Whereupon, the question is read back</p> <p>16 by the reporter.)</p> <p>17 A Correct.</p> <p>18 Q Doctor, on page 29 of your report, and</p> <p>19 you're welcome to refer to it, you opine that</p> <p>20 Ethicon had at its disposal a number of safer</p> <p>21 feasible alternative designs that could have</p> <p>22 been utilized instead of the Prolift kits,</p> <p>23 correct?</p> <p>24 A That's correct.</p>

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<p>1 Q Two of the things that you mentioned</p> <p>2 are elimination of the mesh arms and elimination</p> <p>3 of the armed blind trocar implantation design,</p> <p>4 correct?</p> <p>5 A That's correct.</p> <p>6 Q Okay. First on the issue of blind</p> <p>7 trocar passage, you have opined in your report</p> <p>8 that one of the features of the Prolift that you</p> <p>9 find to be unreasonably dangerous is the blind</p> <p>10 trocar passage, correct?</p> <p>11 A That is correct.</p> <p>12 Q Isn't it correct that the TVT</p> <p>13 Retropubic involves a blind trocar passage?</p> <p>14 A It's specific to the anatomy in the</p> <p>15 place of where the trocars are passed. That's</p> <p>16 what makes the difference.</p> <p>17 Q What do you mean?</p> <p>18 A What I mean is that if you pass blind</p> <p>19 trocars in TVT Retropubic, the -- there's a</p> <p>20 place we call the safe zone. The safe zone of</p> <p>21 the tip of those trocars has a lot of latitude.</p> <p>22 It can deviate 2 or 3 centimeters to the lateral</p> <p>23 side before you hit a vital structure that will</p> <p>24 injure the patient.</p>	<p>1 TVT compared to the passage of these other</p> <p>2 needles and I know that because I've passed</p> <p>3 those needles on live human beings.</p> <p>4 Q So am I correct that your opinion about</p> <p>5 the blind passage, your concern is not that the</p> <p>6 passage is blind, your concern is about the path</p> <p>7 that the trocar is taking; is that correct?</p> <p>8 A Correct. I mean, I pass blind -- a</p> <p>9 trocar is when I implant a nerve stimulator on</p> <p>10 an InterStim, on the back, that I tunnel</p> <p>11 distances of sometimes 15 or 20 centimeters</p> <p>12 blindly, but under the skin on your back, the</p> <p>13 only thing that there is is just fat and some</p> <p>14 underlying muscle. There's no major vessels or</p> <p>15 nerves back there. The same thing applies to</p> <p>16 the TVT.</p> <p>17 Q Is it correct that every sling that</p> <p>18 you've ever placed has involved a blind trocar</p> <p>19 passage?</p> <p>20 A No, that's not true.</p> <p>21 Q Which ones don't?</p> <p>22 A If I do a fascial -- a fascial sling or</p> <p>23 I do a muscle sling, oftentimes I'll open those</p> <p>24 patients abdominally and then I'll make a tunnel</p>
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<p>1 In the passage of the TOT, and I never</p> <p>2 found this to be problematic in terms of -- in</p> <p>3 terms of injuring a structure at the time of</p> <p>4 placement, but I found it to be a problem later</p> <p>5 in TOT was when -- was when the mesh contracted</p> <p>6 and caused the problem, which is why I stopped</p> <p>7 using it.</p> <p>8 But specifically in the passage of the</p> <p>9 needles that go back towards the sacrospinous</p> <p>10 ligament or towards the arcus tendineus near the</p> <p>11 ischial spine, your safe zone is much smaller</p> <p>12 and the risk of injuring a vital structure is</p> <p>13 much higher.</p> <p>14 And that structure as it passes lateral</p> <p>15 to the rectum can be a rectal perforation, it</p> <p>16 can be injuring the plexus vessels that run in</p> <p>17 the lateral space next to the rectum. It can be</p> <p>18 either a pudendal nerve or artery that run just</p> <p>19 inferior to the pudendal -- to the sacrospinous</p> <p>20 ligament or the coxalgias muscle. It can be</p> <p>21 injuring other vessels that are in that area or</p> <p>22 other small nerves like the splanchnic nerves.</p> <p>23 So I find, again, it's like comparing</p> <p>24 apples to oranges with the blind passage on the</p>	<p>1 lateral to the urethra.</p> <p>2 Q Let me be more precise in my question.</p> <p>3 Am I correct that every synthetic mesh sling</p> <p>4 that you've implanted has involved a blind</p> <p>5 trocar passage?</p> <p>6 A I believe so.</p> <p>7 Q And of those, I think about -- you've</p> <p>8 told me about 300 have been from an obturator</p> <p>9 approach, correct?</p> <p>10 A Correct.</p> <p>11 Q And the obturator approach takes the</p> <p>12 obturator sling through the same area that the</p> <p>13 Prolift anterior mesh arms go through, correct?</p> <p>14 A That's correct.</p> <p>15 Q In 2010, Ethicon came out with a pelvic</p> <p>16 mesh kit, prolapse repair kit called Prosima,</p> <p>17 are you familiar with Prosima?</p> <p>18 A Only superficially.</p> <p>19 Q When you say "only superficially," what</p> <p>20 do you mean?</p> <p>21 A I didn't use it and I don't recall</p> <p>22 spending a lot of time looking into the</p> <p>23 literature regarding Prosima.</p> <p>24 Q So do you understand that Prosima does</p>

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<p>1 not have mesh arms and does not involve the use</p> <p>2 of trocars?</p> <p>3 A Yes.</p> <p>4 Q But you did not ever try Prosima,</p> <p>5 correct?</p> <p>6 A I did not.</p> <p>7 Q And you have not reviewed in</p> <p>8 preparation -- strike that.</p> <p>9 You have not reviewed the medical</p> <p>10 literature addressing Prosima in preparing your</p> <p>11 opinions in your report, correct?</p> <p>12 A That's correct.</p> <p>13 Q You also mention polyvinylidene</p> <p>14 fluoride, and then you have in parentheses,</p> <p>15 PVDF/PRONOVA. What is PVDF and what is PRONOVA,</p> <p>16 are they the same thing or different things?</p> <p>17 A PVDF is the basis of the PRONOVA mesh.</p> <p>18 Q Is PRONOVA a mesh?</p> <p>19 A It's a mesh.</p> <p>20 Q Where is PRONOVA -- is PRONOVA</p> <p>21 available --</p> <p>22 A I don't believe it is available. It's</p> <p>23 available to -- internally to the company that</p> <p>24 makes it, which is Johnson & Johnson, but I</p>	<p>1 opinion proposing PVDF/PRONOVA as a proposed</p> <p>2 alternative design is based solely on company</p> <p>3 documents that you have reviewed in your role as</p> <p>4 an expert?</p> <p>5 A Yes.</p> <p>6 Q So if there is -- so fair to say you</p> <p>7 have not reviewed any medical literature on the</p> <p>8 application of PVDF in a hernia application,</p> <p>9 correct?</p> <p>10 A That was not something that I was</p> <p>11 looking at, no.</p> <p>12 Q And am I correct that you have not</p> <p>13 reviewed any medical literature assessing PVDF</p> <p>14 or PRONOVA in an indication -- or let me start</p> <p>15 that over again.</p> <p>16 You have not reviewed any medical</p> <p>17 literature assessing PVDF or PRONOVA to treat</p> <p>18 pelvic organ prolapse, correct?</p> <p>19 A I only mentioned it because the</p> <p>20 internal documentation showed that -- that</p> <p>21 Ethicon's own people were considering this as an</p> <p>22 alternative because they thought it was a better</p> <p>23 material. That's the only reason that I</p> <p>24 included it in here, was I followed the guide</p>
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<p>1 don't believe at this time that it's</p> <p>2 commercially available.</p> <p>3 Q Am I correct that you are not aware --</p> <p>4 strike that.</p> <p>5 Am I correct that FDA has never cleared</p> <p>6 or approved PRONOVA for use in the United States</p> <p>7 to treat pelvic organ prolapse; is that correct?</p> <p>8 A I don't know for a fact, but I believe</p> <p>9 it is correct.</p> <p>10 Q Am I correct that FDA has never cleared</p> <p>11 PVDF mesh for use in the United States to treat</p> <p>12 prolapse?</p> <p>13 A I don't believe so.</p> <p>14 Q Have you ever used PVDF or PRONOVA</p> <p>15 mesh?</p> <p>16 A I have not.</p> <p>17 Q Have you ever -- to your knowledge, are</p> <p>18 there any studies published in the medical</p> <p>19 literature about the use of PVDF or PRONOVA for</p> <p>20 pelvic organ prolapse repair?</p> <p>21 A I think the only literature I reviewed</p> <p>22 regarding PVDF was based on internal</p> <p>23 documentation from Johnson & Johnson.</p> <p>24 Q Am I correct, Dr. Garely, that your</p>	<p>1 from Ethicon.</p> <p>2 Q But you are not aware of any clinical</p> <p>3 studies that actually assess whether PVDF or</p> <p>4 PRONOVA would be safe and effective when used to</p> <p>5 treat prolapse, correct?</p> <p>6 A Correct.</p> <p>7 Q You're not aware of any such data,</p> <p>8 right?</p> <p>9 A Correct.</p> <p>10 Q And am I correct that your opinion on</p> <p>11 PVDF or PRONOVA as an alternative design is</p> <p>12 based on your inferences of what Ethicon knew</p> <p>13 about PVDF?</p> <p>14 A It wasn't so much of an inference as it</p> <p>15 was just restating what was stated in the</p> <p>16 internal documentation, which was they, the</p> <p>17 people in the documents that were provided to</p> <p>18 me, had opined that they thought PVDF would be a</p> <p>19 better alternative than polypropylene.</p> <p>20 Q Isn't it correct that the people at</p> <p>21 Ethicon who were discussing that were</p> <p>22 considering PVDF as an alternative as they</p> <p>23 consider lots of materials as alternatives --</p> <p>24 well, strike that. Am I correct</p>

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<p>1 that you have not seen anything in the company 2 documentation where anyone made a conclusion 3 based on medical evidence that PVDF was safer 4 than Gynemesh PS? 5 A I don't know if it's a conclusion if 6 someone says maybe we should use PVDF because it 7 might be better than Prolene. I don't know if 8 that's a conclusion. 9 Q When someone says maybe we should use 10 PVDF, that's an indication that they are 11 exploring other options, correct? 12 A Correct, because they wanted to explore 13 other options because they knew they had a 14 problem with their product as it was. 15 Q Doctor, you've done a lot of work with 16 Ethicon and other companies as a consultant, 17 correct? 18 A Correct. 19 Q And you know very well that part of the 20 business of being a medical device manufacturer 21 is that you are always looking for new 22 iterations and new innovations to the products 23 that you already offer, correct? 24 A Again, in a vacuum, you can't just say</p>	<p>1 and they chose to continue promoting their 2 product. And by the way, we're now going to 3 look at some alternatives. 4 MS. KABBASH: Move to strike everything 5 after "Ethicon." 6 BY MS. KABBASH: 7 Q Doctor, am I correct that your opinion 8 proposing PVDF and PRONOVA as an alternative 9 safer design is not based on any published or 10 unpublished medical literature that studies the 11 use of this mesh to treat prolapse in women, 12 correct? 13 A Only based on what I saw from Ethicon. 14 Q Only based on what you read in the 15 company documents, correct? 16 A Correct. 17 Q And what you interpreted as what 18 Ethicon believed or knew about PVDF at that 19 time, correct? 20 A More or less, correct. 21 Q Doctor, you've issued several opinions 22 relating to the warnings that Ethicon has issued 23 in relation to Prolift and Prolift+M, correct? 24 A I have.</p>
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<p>1 that sentence without taking into account all 2 the other things surrounding your assumption. 3 Yes, you want to always come up with new and 4 more innovative products. 5 Q Just because a company is considering a 6 particular material as a basis for a new product 7 does not mean that it has concluded that prior 8 products are defective or problematic, correct? 9 A In this particular case, they were 10 considering alternatives because they had a 11 product that was problematic. 12 Q And that's based on your opinion, 13 correct, not what -- not any position that 14 Ethicon is taking, correct? 15 A No, that was based on the opinion of 16 Ethicon. They themselves were revealing in 17 their own internal documentation that they knew 18 they had a problem. They wanted to change the 19 IFU, but there was a printer -- the product had 20 already gone to the printer and they didn't want 21 to make a change in the printing. 22 There were many instances when Ethicon 23 knew that they had a product that was plagued 24 with problems, that were going to hurt people,</p>	<p>1 Q Your opinions obviously are that the 2 warnings accompanying Prolift and Prolift+M are 3 inadequate, correct? 4 A They're incomplete. 5 Q Okay. What do you mean by that? 6 A Well, you'd have to show me where the 7 list is because off the top of the head, I 8 don't -- I don't know what's missing and what's 9 not. 10 Q What generally do you mean by 11 "incomplete," are you saying you're not taking 12 issue what's in the IFUs, but you believe that 13 more should be in there; is that what your 14 opinion is? 15 A My opinion is that -- that there's a 16 little bit of deception in the IFU because they 17 don't fully disclose what the severity of the 18 complications can be. There's a big difference 19 between saying a patient can have pelvic pain, 20 as opposed to this person is going to have 21 lifelong pelvic pain even if this material is 22 explanted. And I don't think 23 that the IFU gave fair warning to surgeons to 24 know that it was going to be extraordinarily</p>

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<p>1 difficult to explant this material. Almost to</p> <p>2 the point where the worldwide medical director</p> <p>3 David Robinson states himself that the</p> <p>4 explanting surgeon, the person who takes it out,</p> <p>5 may need even more skill than the person who</p> <p>6 puts it in because the -- and I have a copy of</p> <p>7 the internal document with me, if you would like</p> <p>8 to see it, where Dr. Robinson makes the</p> <p>9 inference that the only people who should be</p> <p>10 explanting the material are people who are</p> <p>11 putting it in because the reputation of the</p> <p>12 product is getting destroyed by all the doctors</p> <p>13 who are taking it out being better trained than</p> <p>14 the doctors who were putting it in.</p> <p>15 Q Doctor, you opine in your report that a</p> <p>16 physician must be warned not only of the</p> <p>17 potential adverse events, but also of frequency,</p> <p>18 severity, duration and potential permanence,</p> <p>19 correct?</p> <p>20 A I'm sorry, can you show me where you're</p> <p>21 reading?</p> <p>22 Q Sure. It's on page 22.</p> <p>23 A Where?</p> <p>24 Q Towards the top of the first full</p>	<p>1 Q Is there any warnings or labeling</p> <p>2 standard outside of your personal opinion that</p> <p>3 you looked to for the opinion that a warning</p> <p>4 needs to include frequency, severity, duration</p> <p>5 and potential permanence?</p> <p>6 A Again, it applies specifically to these</p> <p>7 two products. If it's -- if there are products</p> <p>8 that don't have permanence and significant</p> <p>9 complications that result in the type of</p> <p>10 severity and duration that these particular</p> <p>11 products have, then I don't think it needs to be</p> <p>12 stated because it wouldn't be true.</p> <p>13 But if you knew that it were true, then</p> <p>14 you should state it. And they did know that it</p> <p>15 were true.</p> <p>16 Q My question is, are you -- is there any</p> <p>17 objective standard or regulatory standard that</p> <p>18 you are pointing to that imposes upon Ethicon a</p> <p>19 duty to include frequency, severity, duration</p> <p>20 and permanence information in its instructions</p> <p>21 for use?</p> <p>22 A I think the only standard would be</p> <p>23 their own credo, their own Ethicon credo of</p> <p>24 doing no harm to patients, following your own</p>
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<p>1 paragraph.</p> <p>2 A Okay.</p> <p>3 Q Do you see that?</p> <p>4 A Yes. So what part did you read?</p> <p>5 Q I read basically the first sentence.</p> <p>6 "The physician must be warned not only of the</p> <p>7 potential adverse events that may be associated</p> <p>8 with the product, but also of the frequency,</p> <p>9 severity, duration and potential permanence of</p> <p>10 adverse events."</p> <p>11 A Sorry. I don't see it. Oh, it's the</p> <p>12 second paragraph.</p> <p>13 Q Yes, first complete paragraph, sorry.</p> <p>14 A So, "In making an informed decision of</p> <p>15 whether or not to use a medical implant, the</p> <p>16 physician must be warned not only of the</p> <p>17 potential adverse events that may be associated</p> <p>18 with the product, but also the frequency,</p> <p>19 severity, duration and potential permanence of</p> <p>20 adverse events." I believe that to be true.</p> <p>21 Q Okay. What is your belief based on?</p> <p>22 Is that your personal opinion about what should</p> <p>23 go into a warning?</p> <p>24 A Yes, I think it is.</p>	<p>1 honor code, your own belief system.</p> <p>2 Q The J&J credo is not a regulatory</p> <p>3 standard, correct?</p> <p>4 A They -- it's their credo. If they</p> <p>5 state it, then they should live to the -- to</p> <p>6 their credo, then why state it?</p> <p>7 Q I appreciate that. But my question is,</p> <p>8 can you point to any Federal regulation,</p> <p>9 guidance or other type of objective standard</p> <p>10 that requires Ethicon's IFU to include</p> <p>11 frequency, severity, duration and permanence</p> <p>12 information? Can you point to such a standard?</p> <p>13 A As I sit here right now, I cannot point</p> <p>14 to it.</p> <p>15 Q Would you agree with me that the 2009</p> <p>16 version of the Prolift IFU did include frequency</p> <p>17 information because it reported the results of</p> <p>18 the -- one-year results of the French and U.S.</p> <p>19 TVM studies?</p> <p>20 A I would have to see the IFU because I</p> <p>21 don't recall the different iterations of it, but</p> <p>22 if you're telling me that's what it said, I will</p> <p>23 believe you and I would have no reason to doubt</p> <p>24 that to be true.</p>

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<p>1 Q If the 2009 version of the Prolift IFU 2 does contain the results of the TVM French and 3 U.S. prospective studies and reports the success 4 rates and the rates of complications on -- 5 complications such as mesh exposure and 6 contraction and other complications, that would 7 speak to -- or that would address your criticism 8 here regarding frequency, severity, duration, 9 correct?</p> <p>10 MR. MATTHEWS: Object to the form of 11 the question.</p> <p>12 BY MS. KABBASH:</p> <p>13 Q You can answer.</p> <p>14 A Well, it -- basically, it's like asking 15 for a do-over. They knew when they released the 16 product, there were problems with it. They went 17 four years with an IFU that didn't state the 18 problems, and then they get a do-over and then 19 they want to put it in and somehow this is going 20 to make the past four years of ignoring what was 21 going on with the product okay.</p> <p>22 So do I think that's a good thing that 23 it's in the new IFU? Of course, but I think 24 they were irresponsible by not doing enough</p>	<p>1 doctors?</p> <p>2 A I was -- I was unfamiliar with the time 3 that it was released, but I know that was the 4 purpose for it.</p> <p>5 Q And this monograph in terms of its -- 6 just the type of document that it is, is similar 7 to the monographs that you participated in for 8 TVT that we looked at earlier today, correct?</p> <p>9 A I think it served the same purpose.</p> <p>10 Q Okay. By the way, this monograph is 11 not cited in your expert report. Is there a 12 particular reason why that's the case?</p> <p>13 A Well, you asked me if I used it to help 14 formulate my opinions.</p> <p>15 Q Yeah, I know this is a different 16 question.</p> <p>17 A Okay.</p> <p>18 Q My question is, I did not see a 19 reference to the monograph in your expert report 20 and I was wondering if there was a particular 21 reason for that?</p> <p>22 A Well, you know, when we write papers of 23 any sort, academic papers, and you want to use 24 footnotes, I usually can find a footnote for</p>
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<p>1 background work on the product before they 2 launched it, and then allowing the IFU not to 3 reflect the severity of the problems that were 4 occurring.</p> <p>5 (Exhibit Garely Garely 16, Document 6 entitled Gynecare Prolift Surgeon's Resource 7 Monograph, marked for identification.)</p> <p>8 BY MS. KABBASH:</p> <p>9 Q I'm going to show you, Doctor, what's 10 been marked as Exhibit 16. Do you recognize 11 this document?</p> <p>12 A I do.</p> <p>13 Q Do you recognize this to be the 14 Surgeon's Resource Monograph that Ethicon put 15 out for the Prolift product?</p> <p>16 A I do.</p> <p>17 Q And when was the last time you reviewed 18 this document?</p> <p>19 A Maybe less than two or three days ago.</p> <p>20 Q Okay. Did you review this document in 21 formulating your opinions in your reports?</p> <p>22 A I did.</p> <p>23 Q Do you understand that Ethicon put this 24 monograph out in 2007 as a training material for</p>	<p>1 every sentence in the entire thing. But I chose 2 to sort of not clog up the entire paper, my 3 expert report, with a thousand references. I 4 tried to use references that I thought were more 5 applicable to the thought process of each 6 section in general. So I don't 7 know that there was anything specific in this 8 report that would have helped me support my 9 position.</p> <p>10 Q Am I correct that you didn't have -- 11 play any role in the generation of this 12 document, correct?</p> <p>13 A No.</p> <p>14 Q Okay. You were not one of the surgeons 15 that was consulted or attended the user forums 16 from which this information came about, right?</p> <p>17 A If I was, I have no memory of it.</p> <p>18 Q Okay. If you look to your report -- 19 Doctor, would you implant PVDF transvaginally in 20 one of your patients?</p> <p>21 A I would not.</p> <p>22 Q You would not?</p> <p>23 A Not based on not knowing clinical data 24 on the product, I would not, or unless I</p>

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<p>1 participated in a study for the product.</p> <p>2 Q That would be -- clinical data on that</p> <p>3 product would be the prerequisite for you to</p> <p>4 consider implanting PVDF in one of your</p> <p>5 patients, correct?</p> <p>6 A Clinical data in the vagina, correct.</p> <p>7 Q Doctor, have you ever seen an IFU for a</p> <p>8 transvaginal mesh implant to treat POP that you</p> <p>9 concluded was adequate?</p> <p>10 A I don't know. I never looked at an IFU</p> <p>11 with that eye. I would have to have all the</p> <p>12 IFUs in front of me, read through them and make</p> <p>13 that assessment. I can't do that right now.</p> <p>14 Q You've reviewed Bard IFUs?</p> <p>15 A I have.</p> <p>16 Q Have you reviewed IFUs of any other</p> <p>17 manufacturers?</p> <p>18 A I reviewed -- for pelvic organ</p> <p>19 prolapse?</p> <p>20 Q Yes.</p> <p>21 A Or for incontinence?</p> <p>22 Q For pelvic organ prolapse.</p> <p>23 A For pelvic organ prolapse, I've looked</p> <p>24 at the Apogee and the Perigee IFUs. I have not</p>	<p>1 that Prolift kits are not well suited for</p> <p>2 patients suffering from stage 1 or stage 2</p> <p>3 prolapse and that the kits are better suited for</p> <p>4 those with more severe prolapse"; that's what</p> <p>5 you say, correct?</p> <p>6 A That is correct.</p> <p>7 Q And then the last line of that</p> <p>8 paragraph says, "Ethicon never provided any such</p> <p>9 warning or information to doctors nor indicated</p> <p>10 in the labeling any limitation on the use of the</p> <p>11 Prolift kits relative to the grade or severity</p> <p>12 of prolapse." That's your opinion there,</p> <p>13 correct?</p> <p>14 A That is my opinion.</p> <p>15 Q If you look at the monograph for a</p> <p>16 second and look to the page on patient</p> <p>17 selection, which is on page 3 of the monograph.</p> <p>18 Do you have page 3, Doctor?</p> <p>19 A I do.</p> <p>20 Q If you look at the first paragraph</p> <p>21 under patient selection.</p> <p>22 A I see it.</p> <p>23 Q It says -- the second line says, "Only</p> <p>24 the treating surgeon can determine where it is</p>
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<p>1 looked at Elevate. What am I missing? I</p> <p>2 have --</p> <p>3 Q Uphold?</p> <p>4 A I have looked at the IFUs for the</p> <p>5 Avaulta products. And Uphold, I haven't looked</p> <p>6 at that one.</p> <p>7 Q Of the ones that you have reviewed,</p> <p>8 have you ever found any of those IFUs to be</p> <p>9 appropriate and adequate in their warnings?</p> <p>10 A Well, I know that the Avaulta products,</p> <p>11 I did not find the IFUs to be adequate or</p> <p>12 appropriate. And I don't recall, it's been a</p> <p>13 long time since I looked at the Apogee, Perigee</p> <p>14 IFUs, I would have to see them again.</p> <p>15 Q So you don't recall what your</p> <p>16 conclusion was about those as you sit here right</p> <p>17 now?</p> <p>18 A Correct.</p> <p>19 Q If you look at page 24 of your report,</p> <p>20 paragraph 4. In that paragraph, you say at the</p> <p>21 bottom, "Ethicon never provided any such warning</p> <p>22 or information to doctors" -- well, in fairness,</p> <p>23 let me start at the beginning. There you</p> <p>24 mention that, "One Prolift clinical study showed</p>	<p>1 best used. Although in patients with previous</p> <p>2 failure, patients with risk factors for failure</p> <p>3 and/or the most severe degree of prolapse, it</p> <p>4 has been very successfully employed and has the</p> <p>5 clearest indications." Do you see that?</p> <p>6 A I do.</p> <p>7 Q Do you believe that that language</p> <p>8 informs doctors that the Prolift is most clearly</p> <p>9 indicated for the most severe degree of</p> <p>10 prolapse?</p> <p>11 A I do not.</p> <p>12 Q Why is that?</p> <p>13 A Because that paragraph doesn't support</p> <p>14 that statement, number one. Number two, if you</p> <p>15 look at the internal documents and the poster --</p> <p>16 Prolift poster presentation made in 2005, which</p> <p>17 I quote as a source in my expert report, from</p> <p>18 9/8/05 by Michael Cosson, quote, "We can</p> <p>19 recommend the use of mesh for Prolift surgery,</p> <p>20 especially patients with big prolapses and</p> <p>21 recurrent prolapses. He said noting that</p> <p>22 women" -- "noting that women with grade 4</p> <p>23 prolapse and greater are better suited for mesh</p> <p>24 surgery than patients with less severe disease."</p>

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<p style="text-align: right;">Page 226</p> <p>1 Q And you don't -- based on what you just</p> <p>2 read, you don't believe that this indication</p> <p>3 that the most severe degree of -- strike that.</p> <p>4 You don't believe that this language in</p> <p>5 the Prolift monograph that says, "The most</p> <p>6 severe degree of prolapse is where it has its</p> <p>7 clearest indications," that is not speaking to</p> <p>8 the same point that is raised by Dr. Cosson?</p> <p>9 A It just says "very successfully</p> <p>10 employed."</p> <p>11 Q "And has the clearest indications,"</p> <p>12 correct?</p> <p>13 A It says that, but it goes on to say</p> <p>14 it's useful in any patient that a surgeon feels</p> <p>15 would require synthetic graft augmentation. But</p> <p>16 that's -- first of all, this is -- this is two</p> <p>17 years after they knew that it wasn't really</p> <p>18 great in patients with minimal prolapse.</p> <p>19 But they still waited two years to put</p> <p>20 this out. And so then now they're saying that</p> <p>21 it's successfully employed and has the clearest</p> <p>22 indications in patients with a constellation of</p> <p>23 things, previous failure, patients with risk</p> <p>24 factors for failure and/or the most severe</p>	<p style="text-align: right;">Page 228</p> <p>1 Q Doctor, what are your opinions -- what</p> <p>2 are your -- strike that.</p> <p>3 What are your opinions about the</p> <p>4 Ethicon and Prolift warnings based on? What</p> <p>5 sources of information is that coming from, your</p> <p>6 opinions about the warnings?</p> <p>7 A Which warnings?</p> <p>8 Q You have several numbered warnings in</p> <p>9 your -- in your report, saying that Ethicon did</p> <p>10 not properly warn of various things, and I'm</p> <p>11 asking what is that coming from? Is that based</p> <p>12 on your personal opinion, based on your</p> <p>13 practice? What is that based on?</p> <p>14 A It's based on my personal opinion, my</p> <p>15 practice and what I've read in the literature.</p> <p>16 Q When you say "the literature," what are</p> <p>17 you referring to?</p> <p>18 A I'm talking about papers that have been</p> <p>19 written about Prolift and Prolift+M with respect</p> <p>20 to their complications.</p> <p>21 Q Is there -- can you point me to any</p> <p>22 peer-reviewed medical literature that concluded</p> <p>23 that dyspareunia is chronic and cannot be</p> <p>24 treated?</p>
<p style="text-align: right;">Page 227</p> <p>1 degree of prolapse. So --</p> <p>2 Q Doctor, I'm sorry. I didn't mean to</p> <p>3 cut you off.</p> <p>4 A I mean, I don't know -- I don't really</p> <p>5 know -- maybe I'm missing the fine point of what</p> <p>6 the question is asking me.</p> <p>7 Q Doctor, am I correct that it's your</p> <p>8 opinion that Prolift should not even be used in</p> <p>9 women with grade 3 and 4 prolapse, correct?</p> <p>10 A I don't understand the question. Can</p> <p>11 you please clarify it? Do you mean presently</p> <p>12 today or back then?</p> <p>13 Q Well, at any point in time, I mean, if</p> <p>14 you don't feel the product is safe today, you</p> <p>15 didn't think it was safe then, right?</p> <p>16 A Well, correct.</p> <p>17 Q So whether or not Ethicon is warning</p> <p>18 about what stages of prolapse are appropriate</p> <p>19 for Prolift, that really has no impact on your</p> <p>20 opinion because your opinion is that even grade</p> <p>21 3 and grade 4 -- even women who have grade 3 and</p> <p>22 grade 4 prolapse should not have a Prolift</p> <p>23 anyway, right?</p> <p>24 A I believe that to be true.</p>	<p style="text-align: right;">Page 229</p> <p>1 A Well, it's always -- it's always a</p> <p>2 tough question to ask a physician, is this going</p> <p>3 to be a permanent condition? Well, it's only</p> <p>4 permanent until you cure it. It's not permanent</p> <p>5 if you cure it. As long as it's ongoing, it's</p> <p>6 permanent unless -- as long -- if the patient</p> <p>7 died today and the patient had the problem, that</p> <p>8 was considered permanent.</p> <p>9 So if you're asking me on a followup</p> <p>10 study of a year or two years, can they make an</p> <p>11 assessment about permanency, it can be implied</p> <p>12 if patients don't get better that are in the</p> <p>13 study. I can speak for myself as a</p> <p>14 doctor who takes care of many of these patients</p> <p>15 that despite multiple removals of the mesh,</p> <p>16 these patients have chronic and ongoing</p> <p>17 dyspareunia and chronic pelvic pain that, in my</p> <p>18 opinion, barring some miracle, they're going to</p> <p>19 have permanency of their complaints.</p> <p>20 Q Am I correct that your opinion that</p> <p>21 patients' injuries, including dyspareunia and</p> <p>22 pelvic pain, is permanent, because that's one of</p> <p>23 your opinions, that that is based on what you've</p> <p>24 seen in your practice and not based on any</p>

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<p style="text-align: right;">Page 230</p> <p>1 particular piece of medical literature that</p> <p>2 you've relied upon?</p> <p>3 A Well, every paper that I've cited in my</p> <p>4 expert report that has followed patients out, I</p> <p>5 don't know that any of those patients that</p> <p>6 have -- any of those papers that have followed</p> <p>7 patients for more than two years have ever said,</p> <p>8 and by the way, we had all the patients in this</p> <p>9 study that had pelvic pain and dyspareunia, 100</p> <p>10 percent of them have had resolution of their</p> <p>11 symptoms, given if the paper were powered</p> <p>12 appropriately. Obviously if</p> <p>13 the paper had a small number of patients,</p> <p>14 there's a statistical chance that some of them</p> <p>15 in that paper may experience resolution. But</p> <p>16 I'm saying that among -- the discussions that I</p> <p>17 have among my peers at professional society</p> <p>18 meetings and among patients that I see in my</p> <p>19 practice and patients that are seen in other</p> <p>20 practices that specialize in the repair of</p> <p>21 transvaginal mesh complications, I can say with</p> <p>22 a hundred percent certainty that there are some</p> <p>23 patients in this -- in my practice that will go</p> <p>24 on to have lifelong dyspareunia and pelvic pain</p>	<p style="text-align: right;">Page 232</p> <p>1 I can tell you that without publishing</p> <p>2 my experience on these patients, that I have</p> <p>3 patients who have permanent disability up until</p> <p>4 this point that I don't know if it will get</p> <p>5 better. So if you're asking me is there a</p> <p>6 publication that says that these patients are</p> <p>7 going to get better?</p> <p>8 No, there's no paper that's going to</p> <p>9 say that these patients are going to get better,</p> <p>10 just like there's no paper that has said we can</p> <p>11 predict with 100 percent certainty that every</p> <p>12 one of these patients is going to have lifelong</p> <p>13 pain. I don't really -- I'm telling you that</p> <p>14 there are patients that are going to be plagued</p> <p>15 with pain for the rest of their lives, barring a</p> <p>16 miracle. That's the best I can do.</p> <p>17 Q And your opinion about that is based on</p> <p>18 what you've seen in your patients, correct?</p> <p>19 A In a very large -- one of the largest</p> <p>20 pelvic surgery practices in the country.</p> <p>21 Q Your practice, correct?</p> <p>22 A My practice.</p> <p>23 Q I just realized, I never marked your</p> <p>24 reliance lists. Let's do that.</p>
<p style="text-align: right;">Page 231</p> <p>1 because they've already seen four or five other</p> <p>2 doctors and have had four or five operations to</p> <p>3 try to relieve the pain and nothing seems to</p> <p>4 work.</p> <p>5 I'm not saying I would give up on them</p> <p>6 and say, okay, you now have permanent pelvic</p> <p>7 pain, you have to live with it for the rest of</p> <p>8 your life and we're just going to accept that.</p> <p>9 I refuse to do that.</p> <p>10 I am always looking for something to</p> <p>11 help and alleviate the chronicity of pain that</p> <p>12 my patients experience. I -- I -- that's one of</p> <p>13 my things that is sort of a hallmark of our</p> <p>14 practice, that we try not to give up on anybody.</p> <p>15 Q You are not relying on any</p> <p>16 peer-reviewed medical literature or any medical</p> <p>17 literature to support your conclusion that</p> <p>18 pelvic pain and dyspareunia following Prolift is</p> <p>19 permanent and not treatable, correct?</p> <p>20 A Anything that's published in the</p> <p>21 literature regarding patients is just someone</p> <p>22 else's experience with their patients. That's</p> <p>23 all they're reporting. They're reporting in</p> <p>24 their experience, this is how our patients did.</p>	<p style="text-align: right;">Page 233</p> <p>1 Doctor, before we do that, would you</p> <p>2 agree with me that the medical literature shows</p> <p>3 that the dyspareunia rates for native tissue</p> <p>4 repairs and for transvaginal mesh repairs are</p> <p>5 equivalent?</p> <p>6 A I do not agree with that.</p> <p>7 Q You don't believe that that's what the</p> <p>8 medical literature shows?</p> <p>9 A I think that -- that there are -- that</p> <p>10 dyspareunia rates, the de novo dyspareunia rates</p> <p>11 are lower in native tissue repairs than in mesh</p> <p>12 augmentations.</p> <p>13 Q Did you tell me earlier that as of</p> <p>14 today, you had not yet reviewed the 2016</p> <p>15 Maher/Cochrane review that came out earlier this</p> <p>16 year?</p> <p>17 A I have not reviewed it.</p> <p>18 Q Do you know Christopher Maher?</p> <p>19 A Not personally, no.</p> <p>20 Q You've read his other publications?</p> <p>21 A Well, I don't know if I've read every</p> <p>22 of his publications, but I've read multiple</p> <p>23 publications.</p> <p>24 (Exhibit Garely Garely 17, Document</p>

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<p>1 entitled Pelvic Organ Prolapse and Sexual 2 Function, marked for identification.) 3 Q I'm handing you what's been marked as 4 Exhibit 17. This article, Doctor, is published 5 in the International Urogynecology Journal, 6 correct? 7 A Correct. 8 Q Have you acted as a reviewer for that 9 journal? 10 A I have. 11 Q And it's a journal that's very well 12 respected in your field, correct? 13 A I believe so, yes. 14 Q This article is entitled Pelvic Organ 15 Prolapse and Sexual Function, and it's 16 co-authored by Viviane Dietz and Christopher 17 Maher, correct? 18 A Correct. 19 Q Did you review this article in 20 preparing your report or in for preparing for 21 this deposition? 22 A I remember looking at or reading this 23 paper when it was first published in the 24 journal. I don't recall if I specifically read</p>	<p>1 de novo dyspareunia compared with traditional 2 anterior colporrhaphy." Do you see that? 3 A I do. 4 Q And then below that in the conclusion, 5 it says, "Sexual function" -- in the second 6 sentence, it says, "Sexual function and 7 dyspareunia rates are similar after anterior 8 polypropylene mesh and anterior colporrhaphy." 9 Do you see that? 10 A Show me that part again. 11 Q Sure. In conclusion. 12 A Oh, okay, fine. 13 Q If you look on the next page, there's a 14 table one. 15 A Okay. 16 Q And that table 1 reflects the 17 metaanalysis of sexual function data from RCTs 18 comparing transvaginal mesh with native tissue 19 repairs, correct, that's what table 1 is? 20 A Yeah, actually, I reviewed this paper 21 in the last week. 22 Q Oh, you did? 23 A I did. Now that I'm looking at the 24 table, I remember that within the last seven</p>
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<p>1 it again as part of the formulation of my 2 opinion. 3 Q And in this study, Drs. Dietz and Maher 4 reviewed several studies that have been done to 5 compare or to address pelvic organ prolapse and 6 sexual function -- strike that. Let me start 7 again. 8 In this article, Drs. Dietz and Maher 9 have discussed that they have reviewed several 10 studies informing their conclusions in this 11 article, correct? 12 A Correct. 13 Q And they say in the abstract, about 14 halfway down, "The highest level of evidence was 15 utilized by the committee to make evidence-based 16 recommendations based upon the Oxford grading 17 system." 18 The Oxford grading system, that's what 19 we discussed earlier, correct? 20 A Correct. 21 Q If you look at the results, the results 22 said, "With regard to anterior compartment, the 23 use of mesh is associated with neither a 24 worsening in sexual function nor an increase in</p>	<p>1 days, I reviewed this paper. 2 Q Okay. And in the -- in the column for 3 De novo dyspareunia, the authors have looked at 4 several RCTs, correct, Altman, Vollebregt, Cary 5 and several others, right? 6 A Uh-huh. 7 Q And they conclude or they find de novo 8 dyspareunia rates for vaginal mesh at 10.6 9 percent and native tissue -- excuse me, and de 10 novo dyspareunia rates of 11.8 percent for 11 native tissue, correct? 12 A Correct. 13 Q And you would agree that those rates 14 that the authors of this study found in this 15 metaanalysis are pretty equivalent? 16 A All I'm going to agree with is what is 17 presented in this paper, but not their 18 conclusions. 19 Q Okay. So you don't agree -- so you 20 acknowledge that what rates are in table 1, they 21 are what they are? 22 A They are what they are. 23 Q But you don't agree -- despite those 24 rates in this metaanalysis that these authors</p>

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<p>1 have found, you don't agree with the conclusion</p> <p>2 that sexual function and dyspareunia rates are</p> <p>3 similar after anterior polypropylene mesh and</p> <p>4 anterior colporrhaphy, correct, you don't agree</p> <p>5 with that conclusion?</p> <p>6 A I'm going to agree with the authors,</p> <p>7 which -- which is their conclusion, which is</p> <p>8 there is a paucity of data on the impact of</p> <p>9 prolapse surgery on sexual function. That says</p> <p>10 it right there. There's no good data. "Sexual</p> <p>11 function and dyspareunia rates are similar after</p> <p>12 anterior polypropylene mesh and anterior</p> <p>13 colporrhaphy grade B. Grade B recommendation</p> <p>14 depends on consistent level 2 and/or 3 studies</p> <p>15 or 'majority evidence from randomized control</p> <p>16 trials.'"</p> <p>17 Q I apologize, where are you reading</p> <p>18 from?</p> <p>19 A I'm reading from the abstract. The</p> <p>20 bottom, right here.</p> <p>21 Q Okay.</p> <p>22 A And so they're not talking about grade</p> <p>23 A recommendations. They're talking about grade</p> <p>24 B. That's not a grade A. And they've already</p>	<p>1 thing with the data here. I applaud Dr. Maher</p> <p>2 for trying to quantify pelvic organ prolapse and</p> <p>3 sexual function. I think that it needs to be</p> <p>4 done.</p> <p>5 And he himself is drawing the</p> <p>6 conclusion that we're just not asking the right</p> <p>7 questions to get the right data. This is not</p> <p>8 what I would call an overwhelming support of</p> <p>9 mesh as having the same outcome as an anterior</p> <p>10 colporrhaphy.</p> <p>11 I certainly don't believe in my</p> <p>12 practice that patients that undergo native</p> <p>13 tissue repairs have the same rate of dyspareunia</p> <p>14 as patients that undergo transvaginal mesh</p> <p>15 procedures. Based on his conclusion, I don't</p> <p>16 even get the sense that he believes that.</p> <p>17 MS. KABBASH: Objection, move to</p> <p>18 strike.</p> <p>19 A Right here, he's says, "Although data</p> <p>20 from randomized controlled trials are valuable,</p> <p>21 sexual function was a secondary outcome</p> <p>22 measurement and most studies are underpowered to</p> <p>23 detect differences in sexual function."</p> <p>24 That's what I remember reading in the</p>
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<p>1 summarized it in the first sentence about the</p> <p>2 paucity of data.</p> <p>3 The studies that they quoted, they</p> <p>4 weren't even powered very well. "We recommend</p> <p>5 using validated questionnaires measuring sexual</p> <p>6 function in women before and after prolapse</p> <p>7 surgery and reporting sexual activity and</p> <p>8 dyspareunia rates pre and post interventions in</p> <p>9 all patients." What they're saying is, garbage</p> <p>10 in, garbage out.</p> <p>11 MS. KABBASH: Off the record.</p> <p>12 (Whereupon, a brief discussion is held</p> <p>13 off the record.)</p> <p>14 BY MS. KABBASH:</p> <p>15 Q Doctor, am I correct that you are</p> <p>16 critical of Dr. Maher and Dr. Dietz's conclusion</p> <p>17 that sexual function and dyspareunia rates are</p> <p>18 similar because you don't believe that the grade</p> <p>19 of the evidence is high enough to make that</p> <p>20 conclusion, correct?</p> <p>21 A When you look at metaanalysis, it's --</p> <p>22 it's like the old doctrine about how you can</p> <p>23 take a sow's ear and put it all together and</p> <p>24 that's not going to make a quilt. It's the same</p>	<p>1 paper during the week.</p> <p>2 Q Can you identify for me any studies</p> <p>3 that analyze abdominal sacrocolpopexy where</p> <p>4 sexual function is a primary end point of the</p> <p>5 study?</p> <p>6 A Not off the top of my head. I do not</p> <p>7 recall.</p> <p>8 Q Can you identify for me any</p> <p>9 metaanalyses that look at grade A evidence</p> <p>10 regarding -- strike that.</p> <p>11 MS. KABBASH: Why don't we take a break</p> <p>12 right now and let's reassess where we are and</p> <p>13 then we'll finish.</p> <p>14 (Whereupon, a brief recess is taken.)</p> <p>15 BY MS. KABBASH:</p> <p>16 Q Dr. Garely, if you go to page 8 of the</p> <p>17 monograph, not 9, would you agree that there are</p> <p>18 several paragraphs going from page 8 on to page</p> <p>19 9 that address mesh complications, erosion,</p> <p>20 exposure and extrusion?</p> <p>21 A I would.</p> <p>22 Q And would you agree that this is a</p> <p>23 fairly detailed description of the risk of mesh</p> <p>24 exposure and erosion?</p>

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<p>1 A I need a minute just to look it over.</p> <p>2 Q Okay.</p> <p>3 A Okay, please repeat the question.</p> <p>4 Q Would you agree that this discussion</p> <p>5 from pages 8 to 9 is a fairly detailed</p> <p>6 description of the risk of mesh exposure and</p> <p>7 erosion?</p> <p>8 A I would not agree.</p> <p>9 Q In the second paragraph under mesh</p> <p>10 complications, it says, "This is to be</p> <p>11 contrasted with the known occurrence of simple</p> <p>12 vaginal mesh exposure. It occurs in</p> <p>13 approximately 3 to 17 percent of cases." Do you</p> <p>14 see that?</p> <p>15 A What they're calling simple mesh</p> <p>16 exposure, yes, I see that.</p> <p>17 Q Does the range of 3 to 17 percent</p> <p>18 that's provided there, would you agree that that</p> <p>19 range appropriately reflects the rates of mesh</p> <p>20 exposure that are reported in the medical</p> <p>21 literature on transvaginal mesh kits?</p> <p>22 A That's not what this says. This says</p> <p>23 "simple vaginal mesh exposure." If you're</p> <p>24 asking me about mesh exposure, I agree. But if</p>	<p>1 in the medical literature fall within this range</p> <p>2 of 3 to 17 percent?</p> <p>3 A Or higher, yes.</p> <p>4 Q What is your understanding of the rate</p> <p>5 of complicated mesh exposures based on your</p> <p>6 review of the medical literature -- strike that.</p> <p>7 What is your understanding of the</p> <p>8 incidence rate of complicated mesh exposures?</p> <p>9 A There's a range, just like there's a</p> <p>10 range in the literature from 3 to 17 percent for</p> <p>11 simple mesh exposures. I -- I would say the</p> <p>12 range is probably somewhere in the range of</p> <p>13 probably close to 5 -- you know, 3 to 5 percent</p> <p>14 is where I would probably go with complicated</p> <p>15 mesh exposures. I'm not saying it's less, but I</p> <p>16 don't know that it's more.</p> <p>17 Q Would you agree with me that most of</p> <p>18 the peer-reviewed medical literature that</p> <p>19 reports mesh exposure rates for pelvic floor</p> <p>20 repair kits reports all mesh exposures at 17</p> <p>21 percent or less except for a few outlier</p> <p>22 studies?</p> <p>23 A I agree with that.</p> <p>24 Q Is there anything else that you believe</p>
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<p>1 you're asking me about simple mesh exposure, I</p> <p>2 do not agree.</p> <p>3 Q What is your understanding of what</p> <p>4 simple vaginal mesh exposure means?</p> <p>5 A A simple mesh exposure is a patient</p> <p>6 that has her surgery and is living a great life</p> <p>7 and has no problems. May notice a little</p> <p>8 spotting, goes to her surgeon. He says, hey,</p> <p>9 there is a little mesh exposed in the vagina, I</p> <p>10 just need to cover it over. That's a simple</p> <p>11 mesh exposure.</p> <p>12 Those are not the kind of mesh</p> <p>13 complications -- which again, I go back to when</p> <p>14 I use the word "I believe it's deceitful." It's</p> <p>15 deceitful in this monograph that they don't</p> <p>16 mention the mesh exposures that are not simple,</p> <p>17 the ones that are complicated, that cause</p> <p>18 chronic granulation and bleeding and chronic</p> <p>19 pain and dyspareunia. This is minimizing mesh</p> <p>20 exposure by using the word "simple." It's</p> <p>21 nothing. It's not nothing.</p> <p>22 Q Doctor, would you agree that all</p> <p>23 incidences of mesh exposure, whether they are</p> <p>24 simple or not, that the rates that are reported</p>	<p>1 is misleading regarding the section on mesh</p> <p>2 complications, exposure, erosion and extrusion?</p> <p>3 A I don't see anything in here where they</p> <p>4 say some mesh exposures are so severe that the</p> <p>5 patient may require a -- a graft to close the</p> <p>6 defect, which is not something that the majority</p> <p>7 of surgeons are capable of using or doing.</p> <p>8 Q Doctor, I -- you explained to me</p> <p>9 earlier that that is your practice, to use a</p> <p>10 graft to close the defect, but can you point me</p> <p>11 to any literature that states that that is the</p> <p>12 standard of care to address a mesh exposure or a</p> <p>13 mesh revision surgery, by using a graft?</p> <p>14 A Absolutely. There are published</p> <p>15 accounts of people using grafts to cover large</p> <p>16 defects. The alternative would be catastrophic</p> <p>17 for the patient.</p> <p>18 Q What literature is that?</p> <p>19 A I -- I would have to go and look in my</p> <p>20 PubMed. I don't recall off the top of my head.</p> <p>21 I think the paper was written by -- give me a</p> <p>22 second.</p> <p>23 Q You know what, I'll strike the</p> <p>24 question. Let's move on.</p>

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<p>1 A Okay.</p> <p>2 Q In the dyspareunia section, you'll see</p> <p>3 that on page 9, there is five paragraphs there</p> <p>4 discussing with doctors the risk of dyspareunia</p> <p>5 and vaginal pain. Do you see that?</p> <p>6 A I see it.</p> <p>7 Q Okay. And one of your criticisms of</p> <p>8 the Ethicon warnings for Prolift is that for a</p> <p>9 period of time contraction was not warned of,</p> <p>10 correct?</p> <p>11 A Correct.</p> <p>12 Q Do you see the last line of this first</p> <p>13 paragraph that says, "Contraction of the mesh</p> <p>14 and/or reduction in the vaginal epithelial</p> <p>15 dimension is the primary exam finding in a</p> <p>16 subset of patients with dyspareunia." Do you</p> <p>17 see that?</p> <p>18 A I see it.</p> <p>19 Q Is it a true statement?</p> <p>20 A I believe it to be a true statement.</p> <p>21 Q And if this document, this Surgeon's</p> <p>22 Resource Monograph, was put out in April 2007,</p> <p>23 then this is a warning that would have been</p> <p>24 available to surgeons at least as of that time,</p>	<p>1 uses any device in the operating room, I know</p> <p>2 that they come with an instructions for use in</p> <p>3 the package.</p> <p>4 Q With regard to the monograph, do you</p> <p>5 have any information -- strike that.</p> <p>6 With regard to the monograph, have you</p> <p>7 reviewed the company internal documents that</p> <p>8 discuss the distribution of this monograph to</p> <p>9 doctors?</p> <p>10 A Of the thousands of pages that I</p> <p>11 reviewed, I do not recall reading anything about</p> <p>12 the distribution of this monograph.</p> <p>13 Q Did you ask to see that information?</p> <p>14 A I did not because it did not occur to</p> <p>15 me that it would be an issue.</p> <p>16 Q That what would be on issue?</p> <p>17 A That I would need to know how they</p> <p>18 distributed this. It just wasn't in the</p> <p>19 spectrum of where I was thinking when I read</p> <p>20 this document, the Surgeon's Resource Monograph.</p> <p>21 Q You certainly don't dispute that this</p> <p>22 document was made available to doctors, correct?</p> <p>23 A I have no basis to dispute it or not to</p> <p>24 dispute it. For all I know, they printed it up,</p>
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<p>1 correct?</p> <p>2 A At least as of that time, but this is</p> <p>3 not the instructions for use, so I don't know</p> <p>4 that -- instructions for use are given to every</p> <p>5 surgeon who's implanting the device every time</p> <p>6 they implant it. I do not know that this</p> <p>7 document was handed out to every surgeon that</p> <p>8 implants this device nor do I know that every</p> <p>9 surgeon was required to read this.</p> <p>10 This wasn't published in any</p> <p>11 literature. This was just handed out by the</p> <p>12 company. I do not have any basis or knowledge</p> <p>13 of who was given this document.</p> <p>14 MS. KABBASH: Move to strike everything</p> <p>15 after "but."</p> <p>16 BY MS. KABBASH:</p> <p>17 Q Doctor, physicians aren't required to</p> <p>18 read the IFU; are they?</p> <p>19 A It depends on your institution. I</p> <p>20 don't know whether your institution requires you</p> <p>21 to read the IFUs.</p> <p>22 Q The manufacturer has no way of</p> <p>23 requiring any doctor to do anything, correct?</p> <p>24 A No, but I know that every doctor that</p>	<p>1 put it in boxes and put it in the basement. I</p> <p>2 do not know.</p> <p>3 Q And it wasn't important to you to find</p> <p>4 out how widely this document was distributed,</p> <p>5 correct?</p> <p>6 A I'm not saying that it wasn't</p> <p>7 important. What I'm saying is that in the</p> <p>8 spectrum of things that I was reviewing in</p> <p>9 preparation for this deposition, and to make and</p> <p>10 formulate my opinions in my expert report,</p> <p>11 wondering whether or how they distributed one</p> <p>12 monograph called the Surgeon's Resource</p> <p>13 Monograph was given out wasn't high on my</p> <p>14 priority list.</p> <p>15 Q Doctor, I'm going to show you what's</p> <p>16 been marked 18.</p> <p>17 (Exhibit Garely Garely 18, Document</p> <p>18 entitled Exhibit B, Dr. Garely's review</p> <p>19 materials, marked for identification.)</p> <p>20 BY MS. KABBASH:</p> <p>21 Q I'm going to show you what's been</p> <p>22 marked as Exhibit 18. And what is that</p> <p>23 document?</p> <p>24 A Exhibit B.</p>

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<p>1 Q Is that Exhibit B to your reports?</p> <p>2 A This is -- it looks like all the stuff</p> <p>3 that I reviewed. Somebody went through it.</p> <p>4 MR. MATTHEWS: Can I answer?</p> <p>5 MS. KABBASH: Sure, go ahead.</p> <p>6 MR. MATTHEWS: Yes. That is Exhibit B</p> <p>7 to his report.</p> <p>8 MS. KABBASH: Okay.</p> <p>9 BY MS. KABBASH:</p> <p>10 Q And does that list contain -- what is</p> <p>11 your understanding of what that list contains?</p> <p>12 A Everything that I reviewed, every piece</p> <p>13 of paper, every document, everything that was</p> <p>14 provided to me that I looked at is documented</p> <p>15 here, like an index.</p> <p>16 Q Did you generate that list or did</p> <p>17 someone else generate that list?</p> <p>18 A Somebody else generated this list.</p> <p>19 Q Did counsel generate it?</p> <p>20 A I believe so.</p> <p>21 Q How many -- what proportion of those</p> <p>22 documents were provided by counsel and what</p> <p>23 proportion were provided by you? I'm not trying</p> <p>24 to hold you to an exact percentage, but can you</p>	<p>1 Q Did you separately find other articles</p> <p>2 that you realized were not already provided to</p> <p>3 you and told counsel, please add this to my list</p> <p>4 because I just found this?</p> <p>5 A No. I think maybe there were things</p> <p>6 that I read that came out after the list was</p> <p>7 done, but I didn't include it in my report.</p> <p>8 MS. KABBASH: I think I'm out of time</p> <p>9 and I don't want to keep you from picking up</p> <p>10 your kids, so I think we're finished.</p> <p>11 THE WITNESS: Good excuse.</p> <p>12 (Time noted: 3:33 p.m.)</p> <p>13</p> <p>14 _____</p> <p>15 ALAN GARELY, M.D., FACOG, FACS</p> <p>16</p> <p>17 _____</p> <p>18</p> <p>19 Subscribed and sworn to</p> <p>20 before me this _____</p> <p>21 day of _____ 2016.</p> <p>22</p> <p>23 _____</p> <p>24 Notary Public</p>
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<p>1 give me a sense of how many of those documents</p> <p>2 came from counsel and how many came from you?</p> <p>3 A Regardless of whether I had them or</p> <p>4 not, a hundred percent of them were supplied by</p> <p>5 counsel.</p> <p>6 Q So I think what you're saying is that</p> <p>7 all of the documents on that list were supplied</p> <p>8 by counsel; you may have already had or seen</p> <p>9 some of them in advance, correct?</p> <p>10 A Correct.</p> <p>11 Q Such as medical literature that you</p> <p>12 happened to have read before you got involved in</p> <p>13 the litigation, correct?</p> <p>14 A Correct.</p> <p>15 Q Okay. Are any of the documents that</p> <p>16 are on Exhibit B there because you did</p> <p>17 independent research and found articles on your</p> <p>18 own that you asked counsel to add to the list?</p> <p>19 A It would be more like a chicken and an</p> <p>20 egg situation, where I asked counsel to provide</p> <p>21 me with all the documents that were -- for</p> <p>22 instance, I said I want a full PubMed search on</p> <p>23 these terms and that's what counsel provided me,</p> <p>24 so...</p>	<p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<p style="text-align: right;">Page 254</p> <p>1 CERTIFICATION</p> <p>2</p> <p>3</p> <p>4 I, DANA N. SREBRENICK, a Notary Public for</p> <p>5 and within the State of New York, do hereby</p> <p>6 certify:</p> <p>7 That the witness, ALAN GARELY, M.D., FACOG,</p> <p>8 FACS, whose testimony as herein set forth, was</p> <p>9 duly sworn by me; and that the within transcript</p> <p>10 is a true record of the testimony given by said</p> <p>11 witness.</p> <p>12 I further certify that I am not related to</p> <p>13 any of the parties to this action by blood or</p> <p>14 marriage, and that I am in no way interested in</p> <p>15 the outcome of this matter.</p> <p>16 IN WITNESS WHEREOF, I have hereunto set my</p> <p>17 hand this 18th day of April 2016.</p> <p>18</p> <p>19 _____</p> <p>20 DANA N. SREBRENICK, CLR, CRR</p> <p>21</p> <p>22 * * *</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 256</p> <p>1</p> <p>2 ACKNOWLEDGMENT OF DEPONENT</p> <p>3</p> <p>4 I, _____, do</p> <p>5 hereby certify that I have read the</p> <p>6 foregoing pages, and that the same is</p> <p>7 a correct transcription of the answers</p> <p>8 given by me to the questions therein</p> <p>9 propounded, except for the corrections or</p> <p>10 changes in form or substance, if any,</p> <p>11 noted in the attached Errata Sheet.</p> <p>12</p> <p>13</p> <p>14 _____</p> <p>15 ALAN GARELY, M.D., FACOG, FACS DATE</p> <p>16</p> <p>17</p> <p>18 Subscribed and sworn</p> <p>19 to before me this</p> <p>20 _____ day of _____, 20____.</p> <p>21 My commission expires: _____</p> <p>22 _____</p> <p>23 Notary Public</p> <p>24</p>
<p style="text-align: right;">Page 255</p> <p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p>	

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